NBSIR 83-2736

Studies of Interface Bondings on Implant Alloys

August 1983

Prepared for:
FDA Contract 22 4795023

NBSIR 83-2736

STUDIES OF INTERFACE BONDINGS ON IMPLANT ALLOYS

Anna C. Fraker, Arthur W. Ruff and Kirk J. Bundy

with

Jacqueline D. Smith, Robert W. Penn, Ann C. Van Orden

August 1983

Prepared for:
FDA Contract 22 4795023

U.S. DEPARTMENT OF COMMERCE, Malcolm Baldrige, *Secretary*
NATIONAL BUREAU OF STANDARDS, Ernest Ambler, *Director*

Studies of Interface Bondings on Implant Alloys

Introduction

This work was initiated for the purpose of investigating mechanisms involved in strengthening or weakening the interface between the metal prosthesis and the bone cement used for prosthesis fixation. This report covers the second year of this investigation. Progress has been made during this study in measurement methods of metal/bone cement interface stength and of assessing the current state of knowledge of cemented prosthesis fixation. This is indicated in the technical report which follows.

The need for increased studies of various aspects of total hip replacement was highlighted by the National Institutes of Health Consensus Development Conference which was held March 1-3, 1982 at the Masur Auditorium on the NIH campus.[1] There are approximately 100,000 total hip replacements made in the United States each year. Each total hip replacement costs around $9,500.[2] Any complications or revisions can result in multiple increases in this figure. The increased pain and problems for the patient are beyond quantification. Nevertheless, the prognosis for total hip surgery is good, and a conservative figure for the success rate is 90 percent. The longer term success rate going beyond 10 years is less well known.

Studies of groups of patients have given figures of 12 percent for prosthesis loosening over a period of 8 years.[3] These data were reported from The Hip Society by Richard J. Johnston, M.D., who emphasized the success of the current mode of total hip surgery and predicted a 75 percent

success rate at the end of 20 years. He cautioned against abandoning this successful procedure in favor of other procedures. Incidences of loosening after 10 years as indicated radiographically have been reported to be as high as 11.3 percent for the acetabular component and 29.9 percent for the femoral component.[4] This radiographic evidence did not indicate prosthesis failure or the need for revision but it did show that the prosthesis fixation was somewhat weakened for its future use. Indications for success in the total hip surgery are at such a high level that it seems feasible to consider that many more of the current failures can be eliminated. Those failures associated with prosthesis loosening originate with the bone/bone cement interface and with the metal/bone cement interface or a combination of both. This study has dealt with the metal/bone cement interface.

Approach

The overall assessment of the prosthesis fixation problem and the state of current scientific research on the subject was made after collecting an extensive literature reference base on the subject. This literature spans a time period of at least 10 years. Expertise of NBS scientists relating to surface films, oxides and other types of films, was used in the initial planning of the experiments. The initial literature review indicated that the torsional loading aspect of the femoral component device had a significant role in the motion of the hip but had received little attention. Based on this, it was decided to pursue this mode of testing. The NBS implant materials torsion fatigue machine, for a period of 3 months, was devoted to the development of a test for the metal/bone cement interface. This fatigue machine was constructed for the purpose of testing implant metals at low frequencies and in appropriate environments

related to surgical implants. After developing and proving the validity of the test, a computer controlled Instron machine capable of torsional loading was used. This machine is located in the Polymers Division and its use involved the cooperation of Dr. Robert W. Penn and other NBS scientists. Dr. Kirk J. Bundy of the Johns Hopkins University has been associated with the Metallurgy Division, National Bureau of Standards during the conduct of these studies. Dr. Bundy has worked with various NBS scientists and student trainees in the conduct of the experimental studies, and he has analyzed the results and prepared two technical reports.

Research Findings

The work performed during the contract year 1982 dealt primarily with testing metal/bone cement interface strength using the torsion test which was developed earlier in this project and described in NBSIR 82 2563. The test proved to be a good one and to be reproducible. The parameters studied to determine their influence on the metal/bone cement interface strength were material type, specimen surface roughness, sterilization and passivation treatments, cure time prior to testing and effects of ultra clean surfaces. Metals used were the alloys, Co-Cr-Mo, Ti-6Al-4V and 316L stainless steel. The bone cement used was Howmedica Surgical Simplex P which is a poly (methyl methacrylate) type.

Results relating to the various parameters indicated interfaces with bone cement and 316L stainless steel to be the strongest followed in turn by those with the Co-Cr-Mo alloy and the Ti-6Al-4V alloy ELI Grade. 316L stainless steel is not used widely as a permanent implant or with bone cement. The influence of surface finish or the degree of surface roughness

on the interface strength varied. Grit blasted or rough surfaces and smooth surfaces with 1 μm finishes gave stronger bonds than did intermediate surface finishes. There was more scatter in the data from the finer surface finished materials even though the overall bond strength was good. This would indicate that the presently used grit blasted surface is the one most advisable to use at the present time. These findings motivated additional research at NBS to investigate mechanisms involved in bonding with a grit blasted (irregularly roughened) surface and with a surface with a 1 μm metallographic polish. This is a joint study involving scientists in the National Measurement Laboratory and the National Engineering Laboratory, two major laboratories at NBS.

The effects of sterilization and passivation treatments on the metal/bone cement interface did not appear to be large in preliminary studies. This is an area where further study would be useful. Specimens subjected to rigorous industrial cleaning showed an average of 25 percent increased interface strength. More testing of procedures utilizing the effects of cleaning would be useful. Cure times of the bone cement after applying to the metal affect the test results for the metal/bone cement interface strength. This work showed that cure times of 2 days or less should not be used and that times ranging from 5 to 7 days would be preferred. The application of increased pressure to the bone cement during the forming of the metal/bone cement interface resulted in increased interface strength. Seventy-seven tests were conducted. The description of these tests, analysis of the results and a discussion of related studies in the technical literature are given in the technical report that follows entitled "An Experimental Investigation Of the Torsional Strength of Metal/Bone Cement Interfaces".

Future Work

Over the past two years, this task has reviewed and established a comprehensive literature base on bone cement interfaces, developed a reproducible test for measuring interface strength ano carried out experiments to obtain data on materials currently used in prosthetic devices. It is clear from our work and research results from other institutions that further advances in improving prosthesis fixation are possible. Clinical data indicate the need for improving cemented prosthesis fixation. Failure requires the patient to undergo further surgery. This surgery and associated rehabilitation are difficult and costly for the patient.

The data obtained on this project during the past contract year indicate that the work described below would be important and beneficial in clarifying mechanisms involved in strengthening the interface. The test which was developed and proved reliable could be used to measure interface strengths of new procedures of implant fixation which now are being used on a clinical trial basis. The proposed work is as follows:

1. Complete the analysis of effects of surface roughness and surface cleanliness on bond strength and explain the role of 2 mechanisms (mechanical and chemical) in strengthening the metal/bone cement bond. Interface strength data will be correlated with refined surface roughness/structure measurements now in progress at NBS.
2. Prostheses which have been precoated with bone cement are in limited use at the present time. Further study is needed to assure that techniques employed in this procedure are an improve-

ment in prosthesis fixation and are beneficial to the patient. NBS proposes to test materials which have been precoated with bone cement where there would be a metal/bone cement and a bone cement/bone cement bond to be considered.

3. Porous coated prostheses are being implanted on a clinical trial basis in an effort to improve fixation. One aspect of the porous coated implants is to achieve fixation by bony ingrowth attachment. Another approach is simply to apply the porous coating in areas where increased interface strength is needed and then to use it with cement. This would be useful for patients who could not get sufficient bony ingrowth. NBS would investigate the porous substrate to determine whether significant bond improvements are obtainable in this way.

Acknowledgments

We wish to acknowledge and express our gratitude for the helpful assistance of a number of individuals and companies. Sidney Weisman, Howmedica, Inc. provided many useful discussions and arranged for Howmedica to supply all of the bone cement used in this project. Ajit K. Kesh of Howmedica provided Co-Cr-Mo specimens and had the satin finish (grit blast) applied to the surface. Charles D. Griffin while at Zimmer, USA arranged for this company to supply some of the Ti-6Al-4V ELI material and conducted grit blasted surface finishing for the Ti-6Al-4V ELI and the 316L stainless steel specimens. 316L stainless steel material was supplied by John Disegi of Carpenter Steel Corp.

Johns Hopkins University students, Michael Vogelbaum, Rob Kelly and Greg Bartlett assisted with specimen polishing and preparation of specimens.

Lewis K. Ives and Clayton Teague of NBS conducted profilometric measurements of the surface roughness. We wish to thank all of these individuals for their help and also Daniel J. Chwirut, Food and Drug Administration, for reviewing and giving constructive comments on the rough draft of the report.

References

1. NIH Consensus Development Conference, Total Hip Replacement, March 1-3, 1982, Gordon, Stephen L., coordinator, National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases.
2. Kelsey, Jennifer L., Yale University School of Medicine, "Epidemiology and Impact," ibid.
3. Johnston, Richard C., The Hip Society, "Long Term Outcomes - Hip Society Collective U.S. Experience," ibid.
4. Galante, Jorge O., Rush Presbyterian-St. Lukes Medical Center, "Total Hip Joint Replacements," ibid.

Disclaimer

Certain commercial materials are identified in this report in order to adequately specify the experimental procedure. In no instance does such identification imply recommendation or endorsement by the National Bureau of Standards nor does it imply that the material is necessarily the best available for the purpose.

AN EXPERIMENTAL INVESTIGATION OF THE TORSIONAL STRENGTH OF METAL/BONE CEMENT INTERFACES

Kirk J. Bundy

TABLE OF CONTENTS

TABLE OF CONTENTS (Cont.)

LIST OF TABLES

LIST OF FIGURES

CHAPTER I

INTRODUCTION AND BACKGROUND

This report describes activities, mainly experimental, pursued in 1982 in the Metallurgy Division of the National Bureau of Standards to study the strength of metal/bone cement (M/BC) interfaces. Although this question is of broader interest, most attention here is focused upon the interface as it affects the total hip replacement (THR). The work described in this report is an outgrowth of that performed in 1981 which was mainly a literature search.

Last year's research results (Bundy, 1982a) have been published in an NBS Internal Report and form the basis for an article submitted to the Journal of Biomedical Materials Research (Bundy, 1982b). Very briefly summarized, that work indicated that failure of the mechanical integrity of the metal/bone cement interface, although not receiving as much attention as failure of the bone/bone cement interface, can lead to failures of the stem component. Hence, it is important both to further understand the biomechanical basis of the failure of the interface and to find means of improving its strength. It was suggested that torsional stresses induced by anterior-posterior forces could be involved in interface failures. A torsion test for the metal/bone cement interface was proposed (because no standard methods of testing exist for this interfacial loading mode) and preliminary experimental data was acquired.

This year's activity has mainly involved an intensive investigation of this torsion test concept and measurements on many samples have been performed to determine what surface is best for improving interfacial strength. This report is divided into seven chapters. Chapter II provides an update of the literature search conducted last year in areas of importance to the performance

of M/BC interfaces. Chapter III describes the materials used and the experimental procedures employed to prepare and test the M/BC interfaces. Chapter IV describes the mathematical analysis for the extraction of the interfacial strength from the measured data. Chapters V and VI contain the experimental results and describe the influence of materials and surface finish, type of surface pretreatment, and other effects on the torsional strength of M/BC interfaces. Finally, Chapter VII provides a discussion and summary of the results, conclusions for this work, and a set of recommendations for future research.

CHAPTER II

LITERATURE SEARCH UPDATE

Although review of the literature was not an area of emphasis for this year's research activities, a certain amount of literature searching was pursued to update and extend the work of last year, and several relevant lines of research were found. These are described briefly below.

Wolff's Law and Bone Remodeling

In last year's report it was pointed out that if Wolff's law (i.e. the idea that bone remodels in response to applied stress) were available in a quantitative form, then mathematical stress analyses and stress measurements of prostheses would be more meaningful in predicting the clinical course of actual or proposed orthopedic procedures. In a series of papers, Cowin and his coworkers have developed a mathematical theory for adaptive elastic materials which they have applied to bone growth, reinforcement, and resorption. (Hegedus and Cowin, 1976a and 1976b), (Cowin and Nachlinger, 1978), (Cowin and Van Buskirk, 1979), (Cowin, 1981), (Cowin and Firoozbakhsh, 1981). The details of the theory are complex, but basically what is involved is solution of the governing differential equations:

$$\varepsilon_{ij} = \frac{1}{2}\left(\frac{\partial U_i}{\partial X_j} + \frac{\partial U_j}{\partial X_i}\right) \tag{1}$$

$$\frac{\partial \sigma_{ij}}{\partial X_j} + \rho \cdot [V_o + e]b_i = 0 \tag{2}$$

$$\sigma_{ij} = [V_o + e]\, C_{ijkl}\,(e)\, \varepsilon_{kl} \tag{3}$$

$$de/dt = a(e) + A_{ij}\,(e)\, \varepsilon_{ij} \tag{4}$$

for the problem of interest.

In the equations above, U_i are displacement components, σ_{ij} and ε_{ij} (or ε_{kl}) denote the stress and strain tensors, X_i (or X_j) denotes the coordinate directions, ρ is the bone material density, V_o is a reference volume fraction of bone material in the porous bone structure, e is the change in volume fraction from the reference due to the adaptive nature of bone, and b_i is the body force.

Equation (1) is the strain-displacement relation for linear elasticity; eq. (2) is the mechanical equilibrium equation; and eq. (3) is a generalized form of Hooke's law. As e approaches zero, and V_o approaches unity the equations reduce to those of linear elasticity theory. Equations (3) and (4) are essentially a mathematical statement of the Wolff's law principle.

Although this theory represents a potentially important advance in understanding of bone remodeling, practical applications will probably have to wait for the future. This is because there have been no experimental determinations so far of the quantities a(e) and $A_{ij}(e)$ whose values would have to be known to make quantitative predictions. The theory up to this point has been used to consider internal remodeling, change in external bone shape, and has indicated that a pure torsion about the long axis of a bone does not induce remodeling.

A paper by Carter et al. contained preliminary steps toward an experimental approach for Wolff's law quantification (Carter et al., 1981). In adult dogs *in vivo* strains were determined with strain gauges attached to the femur. Stresses were calculated using bending theory and finite element calculations. Normal femurs and those in which an orthopedic plate had been implanted were measured. Metabolic activity was monitored using tetracycline labeling techniques. It was observed that alterations in stress field do appear to induce bone remodeling. Perhaps, with development and refinement, techniques such as this could become useful for expressing Wolff's law in a quantitative form.

Frequency of Total Hip Replacement Surgery

Several papers have come to our attention which discuss the numbers of total hip replacements performed every year. This is an important subject with respect to implant failures because the number of failures must in some manner be proportional to the number of operations performed.

Hori et al. (1978) studied Medicare and Veterans Administration data, sent a questionnaire to all orthopedic surgeons in Illinois and to selected prominent surgeons throughout the U.S., consulted sales figures of orthopedic equipment companies, and investigated admissions data of a large number of hospitals. The time period spanned in this study was 1972-6. Estimates of the numbers of artificial joints implanted in 1976 derived from these sources were: total hip replacement - 80,000; total knee replacement - 40,000; other joints - 10,000. From the questionnaire it was estimated that, were perfect designs available, the numbers of procedures performed on the population would be 12%, 60%, and 240% greater, respectively for these three categories.

At the March, 1982 NIH Consensus Development Conference a paper was given which contained statistics regarding total hip replacements (Kelsey, 1982). The 1979 estimate of the number of total hip replacements performed was 70,000 artificial joints in 61,000 patients. The age distribution of the patients was 57% - greater than 65 years old, 25% - 55 to 65 years, and 18% under age 55. With respect to the reasons for surgery, the most commonly mentioned factors and their frequencies were 60% osteoarthrosis, 11% hip fractures, 7% rheumatoid arthritis, 7% aseptic necrosis, and 6% replacement of previously inserted devices. This amounted to a $700,000,000 annual expenditure including treatment for late infections. Ninety percent of hip operations are considered successful after a 10 year follow up period.

In a Workshop on Internal Joint Replacement held at Northwestern University in 1977 it was estimated that in the U.S. in 1976, there were 120,000 total joint replacements which comprised 80,000 hips; 30,000 knees; 8,000 fingers; and 2,000 others (ankles, shoulders, elbows, wrists) (Compere and Lewis, 1977). It was estimated that due to increasing reliability of prostheses and an aging population, the number of artificial joints will increase to over 180,000 in the future.

Another estimate of the number of joint replacement operations was contained in a study by the Office of Technology Assessment. (Bentkover and Drew, 1981). According to this report, U.S. annual figures are: 100,000 hip replacements, 50,000 knee replacements, and 12,000 replacements of other joints. Annual sales of joint implants are estimated at $114,000,000 of which the two leading companies account for two-thirds of the total.

Pre-Coating of Implants with Bone Cement

A number of papers have appeared recently (Park et al., 1979), (Barb et al., 1982), (Park et al., 1982), (Raab et al., 1982) which describe a concept which could have an important relationship to the present work. This is the idea that the M/BC interface could be pre-formed before implantation. The beneficial aspects of this type of fabrication would be, 1) a smaller amount of the toxic monomer released during the operation, 2) lessened heat production and volumetric shrinkage during polymerization, 3) better positioning of the implant in the medullary cavity, and 4) increased interfacial strength.

With respect to the latter point, in one study (Barb et al., 1982) push-out tests were performed on retrieved canine hip prostheses with circular cross-sections and sand blasted surfaces after various service times *in vivo*.

Both pre-coated and non pre-coated samples were used. The coating consisted of a layer of surgical bone cement about 2 mm thick and was applied by injection into a mold with a syringe. The interfacial shear strength was 17.2 MPa after one month for pre-coated implants and leveled off at about 12 MPa at three months. This was about 2-3 times stronger than conventionally formed interfaces. According to these investigators, the reasons that the interfacial shear strength decreases with time is possibly "due to stress relaxation caused by the body fluids diffusing through bone cement, i.e., plasticizing the bone cement or relaxation of locked-in hoop stress caused by the shrinkage of bone cement."

The old bone cement/new bone cement interface increased in strength with time and reached a value of 18.7 MPa (as expected, a value higher than the M/BC interface since direct chemical bonding is involved). The bone cement/bone interfacial strength declined from proximal to distal locations due to lessened trabecular interdigitation. Interestingly, even the bone cement/bone interfaces were stronger for the pre-coated samples (1.6-2.3 MPa) as compared to conventional interfaces (0.8-1.6 MPa).

The latter finding indicates that production of a strong M/BC interface will apparently lead to a retention of strength of the bone/bone cement interface. Since loosening of the latter interface is an important clinical problem, any treatment which increases M/BC interfacial strength could potentially improve the clinical success rate of total hip replacements. In a further study, this group demonstrated that the mass density of pre-coated bone cement (1.202 g/ml) was about 2% higher than nonpre-coated cement and that the pre-coated cement elicited milder histological reactions (Park et al., 1982). The reason that pre-coated bone cement has a higher density is that there are no large voids or inclusions of blood and marrow fat within it.

Raab et al. (1982) refined the pre-coating concept. Instead of using surgical cement for the coating, an industrial type of procedure was followed to enhance wetting. The metal surface was rigorously cleaned and then dipped in a lacquer-type solution of PMMA in MMA which contained no catalysts or radio-opaque agents. A silane coupling agent (gamma methacryloxypropyltri-methoxy silane, A-174 Union Carbide Can. Ltd.) was added to provide resistance to environmental degradation in saline solutions. The interface was annealed by curing above the glass transition temperature of PMMA to relax residual stresses.

Raab et al. found similar degrees of interfacial shear strength increase as described above when comparing pre-coated to uncoated samples: 316LVM-19.1 and 11.2 MPa respectively, Co-Cr-Mo-15.3 and 6.9 MPa, and Ti-6Al-4V-19.2 and 12.5 MPa. Among the influential variables related to interface strength were the PMMA/MMA ratio in the dip (which is related to contact angle) and use of ultrasonic cleaning (which was shown to adversely affect Ti-6Al-4V interfacial strength). Improvements due to pre-coating were more observable when interfaces were tested dry than for 37 °C saline conditions. Other important observations were that; 1) silane additions had a markedly beneficial effect, 2) for pre-coated metals in saline the fracture toughness of the interface is comparable to that of the bone cement itself and the fatigue life is much greater than for non-pre-coated samples tested dry, and 3) these coatings can be sterilized in a practical manner.

This pre-coating concept is an exciting one for the reliability of total hip replacement. It offers a way to improve markedly interfacial strength and hence to diminish the incidence of stem fracture. The high pressure interface formation technique described later in this report could also be practically applied to form coatings remotely. Since the evidence described later implies

that this method produces stronger interfaces than conventional techniques, there may be direct clinical relevance for the research work pursued here.

There is good ground for optimism, based on these studies cited above and the work presented later in this report, that using a pre-formed interface (for which surface cleaning, surface finish, interfacial pre-forming pressure, and bone cement composition is optimized) a substantial level of interface strength improvement could be obtained. An interesting concept along these lines is the application of an electrical potential across the interface as cement is curing to possibly influence bonding characteristics.

Properties of Bone Cement and Metal/Bone Cement Interfaces

The determination of properties of bone cement is still a very active field of research and a number of papers of interest have recently appeared. Krause et al. (1982) studied rheological properties of several cements in detail and concluded that they are non-Newtonian, pseudoplastic materials with constitutive laws of the form:

$$\tau = K(\dot{\gamma})^n$$

(where τ is shear stress, $\dot{\gamma}$ is shear strain rate, and K and n are constants) for which $n < 1$. This means they have a rate dependent viscosity:

$$\eta = K(\dot{\gamma})^{n-1}$$

which decreases with increasing shear rate.

Creep and stress relaxation of bone cement have been studied by Holm (1980) and Pal and Saha (1982). Bone cement possibly can develop large residual stresses during curing as the volumetric shrinkage is constrained by the surrounding bone and femoral component. Bone cement will creep under applied load and will relax stresses at a constant deformation. It is thought that these characteristics can lead to cement fracture and loosening and failure of total hip replacements. Reduction in the degree of bone cement porosity and use of graphite fibers for reinforcement can reduce time dependent behavior.

With respect to the M/BC interface, Welch et al. (1971) performed push-out tests on interfaces in which the metals and finishes used were porous vitallium, "satin-surfaced" vitallium (presumably a finish comparable to what has been termed "grit blasting" later in this report, and "buff polished" stainless steel. Five samples per material were tested and interfacial shear strength ranges were respectively determined for these three cases to be: 122-190, 37.3-42.9, and 40.8-46.4 kg/cm^2. Use of a porous metal/bone cement interface is an interesting concept for the total hip replacement and apparently could increase interfacial strength considerably. However, lack of interface mechanical integrity would expose much higher surface areas of metal to body fluids and consequently perhaps to increased possibilities of adverse biological systemic effects resulting from injection of metallic ions into solution by dissolution if these effects are proportional to the amount of ion release.

Mathematical modeling of the bone/bone cement interface was examined by Sih, Moyer, and Berman (1981) using a strain energy density (i.e. fracture toughness) criterion for failure instead of the usual stress criteria. The same ideas could be applied to M/BC interfaces.

Total Hip Replacement Stress Analyses

A number of interesting papers related to stress analyses of total hip replacements were reviewed. Crowninshield et al. (1981) performed three-dimensional finite element analysis (FEA) with forces applied at various angles in the medial-lateral plane and considered the stresses in the bone cement and bone for different combinations of collarless and collared prostheses made from Ti alloys or stainless steel. It was shown that, for collarless prostheses, the more flexible Ti stem produces higher cement stresses in the proximal region and lower stresses in the distal region. With collar-femur contact (a situation these authors believe would be very difficult to achieve clinically) increased femoral stresses and decreased cement stresses result.

These researchers feel that cement failure proximally rather than distally is a more major clinical cause of loosening and thus that the implant should be made of stiffer materials. They feel that proximal bone resorption, although it occurs, is not causally related to loosening.

Huiskes (1980) also performed three-dimensional finite element analysis of THR's. His results demonstrated that except in the proximal region, the femur and the stem could be analysed with beam theory (which is a two-dimensional analysis) but that accurate determination of stresses in bone cement required a three-dimensional analysis. This investigator is sensitive to the variation of results of stress analyses with respect to the orientation of joint force components as the angle of the joint force in the medial-lateral plane deviates from the vertical and cautions against deriving general conclusions regarding a device based upon one specific physiological load. This latter point is an important one. Hopefully at some point in the future three-dimensional FEA will be performed for a realistic series of hip joint force components which will include anterior-posterior forces which produce torsional loading.

McNeice et al. (1976) performed an FEA study of THR's and concluded that M/BC interface loosening is a strong possibility due to the large shear stresses generated in the stem due to joint forces which act in the medial-lateral plane. 17.5 MPa maximum shear stresses occur on the inferior aspect near the stem neck and at the distal lateral surface. Assuming that impact loading would double these values, the shear stress in the stem would approach the shear strength of acrylic. They also analysed several modes of THR loosening. The most devastating one, although not the clinically most common mode, is the cantilever fatigue mode in which M/BC interface integrity is lost proximally (thus losing the support and stiffness of the bone which resists bending in an

intact structure). This produces high bending stresses and fatigue failure. An interesting metallurgical analysis of such a case is found in a recent paper (White et al., 1979).

In a very careful clinically oriented statistical study of femoral stem fractures this mode of failure was observed to be the most common (Chao et al., 1981). Among the most frequently implicated variables in stem fracture are: cancellous bone removal from the calcar, poor bone cement quality on the proximal medial part of the stem, stress concentrations due to nick marks from the drill bit during trochanter reattachment, and cement build up at the base of the neck. This paper by clinicians does mention that examination of fracture surfaces shows evidence that, in addition to loads which cause lateral bending, loads which cause anterior-posterior bending and torsion are also important. As was pointed out in last years report, although clinicians have made this observation (Wroblewski, 1979), (Charnley, 1975), (Chao et al., 1981) stress analysts do not seem to have placed sufficient importance on the three-dimensional nature of the joint loads at the hip.

In an experimental study, Lanyon and his coworkers (1981) implanted strain gauges on the surface of sheep femora and determined the strain pattern during walking for intact bones and for femora which had undergone a total hip replacement operation. Strains on the lateral part of the proximal portion of the femur shaft indicated that torsion about the long axis of the femur was present at this location. Although there obviously are differences between the animal model and the human hip, these results are perhaps one additional indication that torsion induced by anterior-posterior forces should be examined with respect to its influence on the total hip replacement, particularly the integrity of the M/BC interface.

CHAPTER III

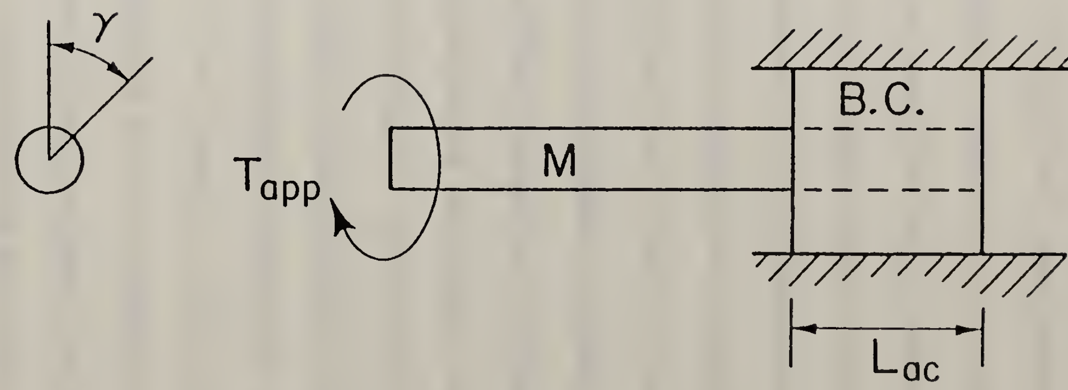
EXPERIMENTAL PROCEDURES

M/BC Interface Formation

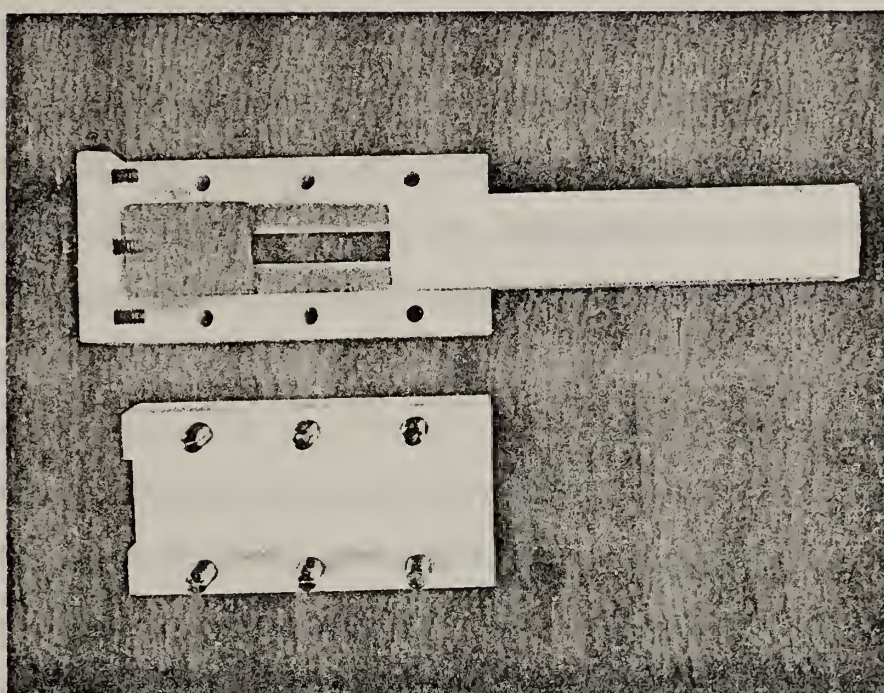
Seventy-seven samples were prepared for testing according to the procedures described in this chapter. The geometry of the specimen is shown in Figure III-1. The manufacturer's directions were followed in mixing of the bone cement (Howmedica Surgical Simplex P). The cement consists of two components: a methyl-methacrylate monomer and a powder which consists of poly (methyl methacrylate) and a methyl-methacrylate styrene copolymer. 10 g of powder was mixed with 5 ml of monomer. This is the same ratio as recommended by the manufacturer; for clinical purposes 40 g of powder are mixed with 20 ml of monomer.

The interface formation time (i.f.t.), i.e., the time between the onset of mixing and the first contact between bone cement and metal, was standardized to four minutes (two minutes for mixing and two minutes for kneading). Standardization of the i.f.t. was thought to be advisable because of monomer evaporation with time and cement viscosity increase with time. Studies where interface strengths of metal/bone cement bonds were measured (for bonds pressurized to a degree similar to clinical conditions) have shown that strength changes with i.f.t. occur (Keller et al., 1980).

The interface was formed through use of the Teflon mold and plunger arrangement shown in cut away view in Figure III-2. The bone cement was packed around the metal rod in about one minute or less. Following this, as much pressure, as was possible to apply by hand, was applied until 10 minutes had elapsed from the onset of mixing. After one hour had elapsed the sample was removed from the mold. Due to losses of material as the procedure above was followed, the length L_{ac} of the acrylic block was somewhat different for each sample prepared.



III - 1   Specimen Geometry



III - 2 Mold Employed to Apply Pressure to Metal/Bone Cement Interface During Specimen Preparation

Although the high pressure technique described above does not closely approximate clinical conditions, the rationale behind its use was the following. First of all, many other variables besides pressure also affect interface formation *in vivo* in the operating theater and would have to be controlled to duplicate the clinical situation. Presumably, when there is great fidelity of the interface formation technique to clinical conditions, there is less control over interfacial strength measurements. The technique used here, on the other hand, seems to offer the advantage of producing a higher quality interface. Better contact of bone cement and metal is achieved so that there is a greater true surface contact area and reduced porosity. Better control over producing the same test conditions for repeated measurements might be expected and is important for the aim of this investigation--to initiate development of methodology to sensitively assess interfacial bond strength in torsion for different surface preparation techniques.

Even though the original idea behind the use of the high pressure technique was to improve control over interface formation, it is possible that the results here could have direct clinical relevance. As previously discussed, to diminish problems associated with thermal necrosis and acute toxicity due to monomer release as polymerization proceeds, there has been interest recently in the concept of pre-forming the metal/bone cement bond so that less cement is polymerized *in situ*. Improvements in mechanical performance could result from this concept. If the use of this technique becomes widespread, then the data from the relatively high pressure technique employed here could be used to compare the relative performance of different materials and surface treatments in torsion if pre-formed interfaces used clinically were fabricated using high pressure.

Materials and Surface Finish

The metal rods used in these studies were the common surgical implant metals: 316L stainless steel, Ti-6Al-4V ELI, and a Co-Cr-Mo alloy. The surface finishes employed were either grit blasted, or polished with diamond pastes for which the finest step was 15μm, 6μm, or 1μm. Specimens were held in a drill press during polishing. The specimen rotated and the polishing paper or cloth was alternately either held in place or moved vertically for the sequential polishing steps. Specimens were polished through a series of silicon carbide polishing papers ranging from a coarse (paper no. 320) to a fine grit (paper no. 600). This was followed by polishing with the diamond pastes to the desired surface finish. The diamond paste polish was applied with polishing clothes which were moistened with mineral spirits. In some cases the surfaces were sterilized and passivated. For these samples steam sterilization (20 minutes at 125 °C) was used. The passivation treatment consisted of 40 minutes immersion in 35.5 % HNO_3 at room temperature. This passivation treatment is in accordance with ASTM Standard F86-76, "Standard Recommended Practice for Surface Preparation and Marking of Metallic Surgical Implants." To obtain the grit blasted surface, we sent samples to the surgical implant companies which supplied the materials used in this investigation. The specimens were glass bead blasted (dry) and cleaned and passivated according to the procedures used to prepare actual implants.

Mechanical Testing Conditions

The M/BC interfaces were tested with a computer controlled biaxial Instron machine capable of simultaneous application of a torsional and a tensile or compressive load. Either the load versus time or displacement versus time are programmable. A holder containing Wood's metal was used to obtain accurate axial alignment.

For the measurements made in this study, except as otherwise indicated, the load consisted of a pure torque applied at a twist rate of 11.25°/sec. This rate was chosen because it corresponded approximately to a rate which would cause yielding in a time interval characteristic of 1/4 of a walking cycle. The yield "strain" estimation was based upon data obtained last year (Bundy, 1982a). The torque versus twist angle data was used to calculate an interfacial shear strength according to the procedure described in the next chapter. The results of the tests are described in Chapters V and VI. The sample set tested and the corresponding mechanical properties are given in Appendices 1-3 which are described later.

Surface Cleaning Procedures

To clean the polished or grit blasted samples the following cleaning procedure was used:

1. One minute of swirling in distilled H_2O containing detergent (Sparkleen, Fisher Scientific Company).
2. One minute running warm tap H_2O rinse.
3. Three minutes ultrasonic cleaning in ethanol.
4. One minute final rinse by swirling in distilled H_2O.
5. Hot air drying.

As a special case, three samples were subjected to an extremely thorough cleaning procedure to test the effect of this variable on the subsequent mechanical behavior of the interface. This procedure consisted of the following steps:

1. One minute of swirling in distilled H_2O containing detergent.
2. One minute running warm tap H_2O rinse.
3. Thirty minutes ultrasonic cleaning in ethylene dichloride (1,2 dichloroethane).

4. Removal of the sample from the ultrasonic cleaner in a closed container so that the sample at no time contacted the surface of the fluid.
5. Hot alkali treatment: cathodic cleaning at -5 volts for one minute in a 95 °C solution containing 59.7 g of Oakite per liter. Oakite is a trade name for a product containing 90% NaOH plus added surfactants, wetting agents, and detergents.
6. Two minute rinse in cold running tap H_2O.
7. One minute rinse in running distilled H_2O.
8. Testing for cleanliness by dipping in 10% HCl.
9. One minute running cold tap H_2O rinse.
10. Two minutes hot tap H_2O rinse.
11. Hot air drying.

Surface Roughness Measurements

The roughness of the surface is an important parameter for the determination of interfacial shear strength (as is described in the next chapter). Profilometric measurements were made on a number of the surfaces tested in this investigation. The surface roughnesses, taken to be twice the arithmetic average roughness, are given in Table III-1. As indicated in the table, some of these values were obtained from actual measurements and some were estimated based upon the measurements with the other materials. These values are probably reliable to within a factor of less than 2, although this is uncertain. Another set of roughness measurements, made by another group of investigators, were seen to be in general agreement with the first set. A typical profilometric trace is shown in Figure III-3. Roughness measurements were taken both when the profilometer stylus was moved longitudinally along the surface parallel to the axis of the rod and also when it was moved circumferentially. The similarity of the results indicates that the polishing procedures used did not induce any

TABLE III-1

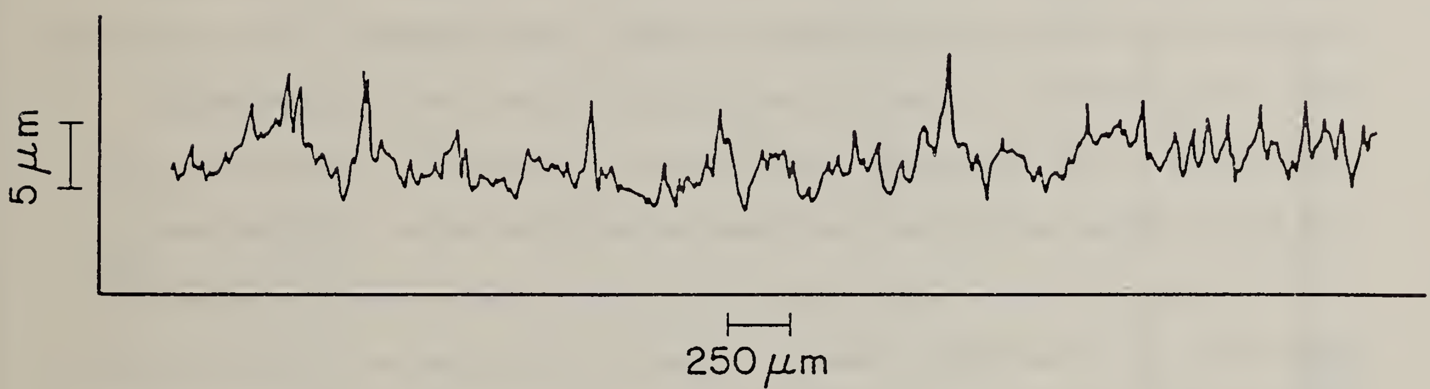
ROUGHNESS OF THE VARIOUS SURFACES OF THE METALS EMPLOYED
TO FORM M/BC INTERFACES

Material	1μm	6μm	15μm	Grit Blasted
316L	12×10^{-8}m*	14×10^{-8}m*	20×10^{-8}m**	140×10^{-8}m
Co-Cr-Mo	12×10^{-8}m*	14×10^{-8}m*	20×10^{-8}m**	166×10^{-8}m
Ti-6Al-4V ELI	12×10^{-8}m*	14×10^{-8}m*	20×10^{-8}m**	205×10^{-8}m

*based upon measurement with 316L.

**based upon average of measurements of 316L & Ti-6Al-4V ELI.

directionality in surface topography which would affect torsional strength measurements. The particular measurement shown in Figure III-3 was taken with the stylus moving parallel to the axis of the rod.



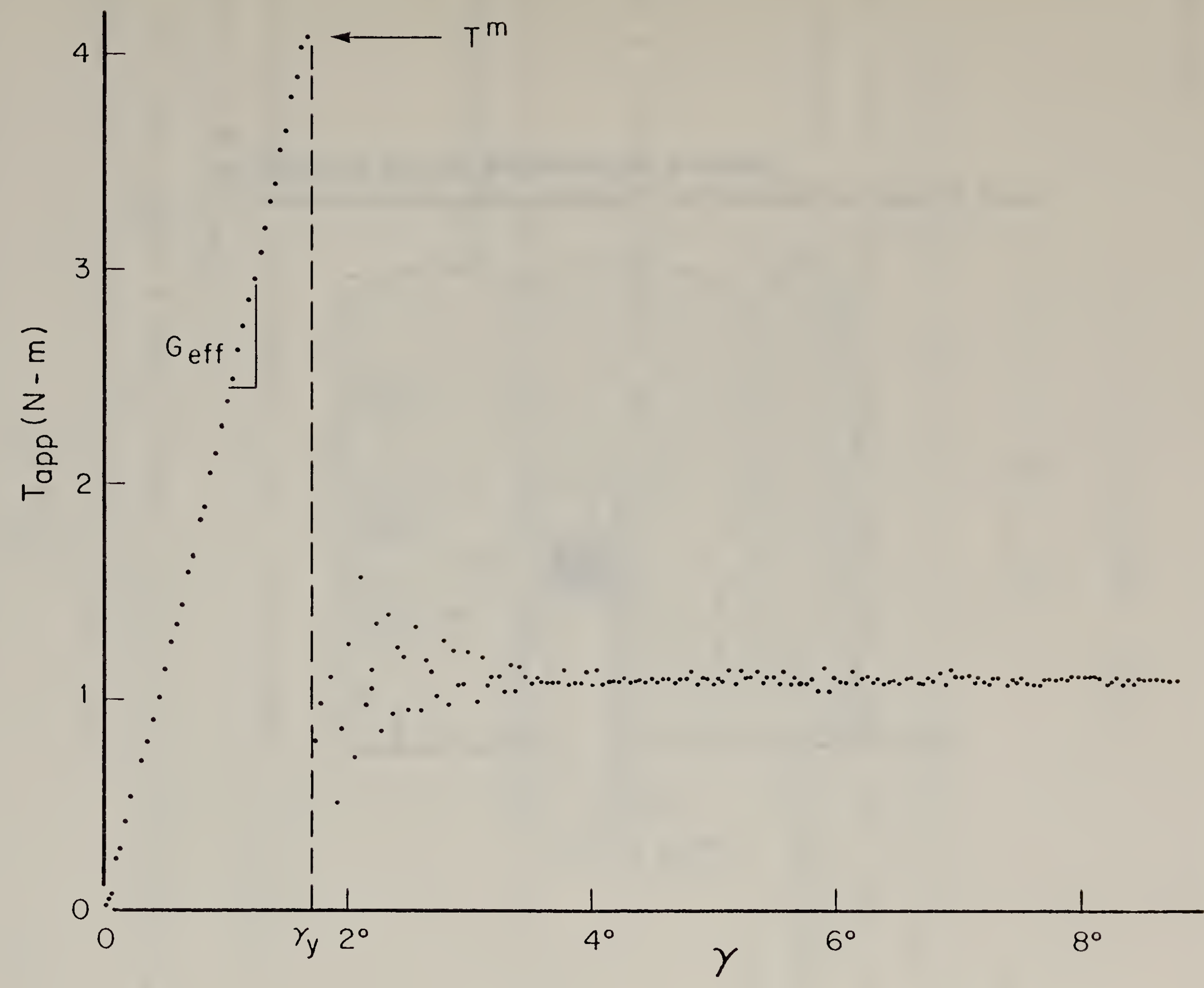
III - 3 Typical Profilometric trace for Measuring Surface Roughness (Ti-6Al-4V ELI Sample with Grit Blasted Finish)

CHAPTER IV

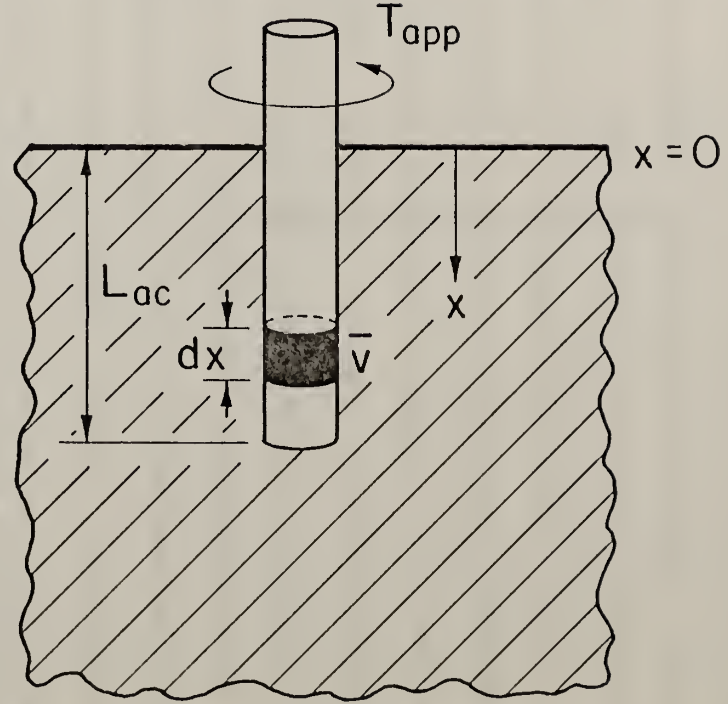
MATHEMATICAL ANALYSIS

Figure IV-1 shows an actual measured torque vs. twist angle curve. It is typical of the type of behavior which was observed for every sample. The data which can directly be obtained from the curve are the maximum torque T^m which corresponds to yielding of the interface, γ_y the twist angle at yielding and the slope $G_{eff} = T^m/\gamma_y$ which is a measure of the elastic behavior of the interface. These parameters are shown in the figure. Since these quantities are sensitive to the length of the acrylic block, it is useful to normalize them with respect to L_{ac}. The normalized torque T^m/L_{ac} is a particularly useful quantity because it is a direct experimental measure of interfacial strength, and unlike the calculated strengths later discussed, it is not based upon any assumptions. Using the raw data available from the experiments, calculation of the interfacial shear stress τ_{if} applied to the surface of the rod by the bonded acrylic was performed as described below. The maximum τ_{if} which can be developed at any point on the surface before failure occurs is a measure of the interfacial strength in torsion. Solution of τ_{if} as a function of position on the surface of the rod can be achieved by modification, and adaptation to torsional conditions, of the shear-lag analysis presented by Greszczuk (1969) for pull-out tests and used by Beaumont and Plumpton (1977) to obtain the shear strength of bone cement/metal junctions from experimental data. The work of Beaumont and Plumpton was considered in more detail in last year's report.

To calculate τ_{if} as a function of position along the rod buried in acrylic, consider the rod buried in acrylic to depth L_{ac} (as shown in cross-section in Figure IV-2). The rod is subjected to an applied torque T_{app}, and the forces



IV - 1 Typical Measured Applied Torque T_{app} vs. Twist γ Angle Curve (Interface 29)



IV - 2 Cross-Sectional Representation of Specimen Geometry with Parameters for the Mathematical Analysis

and moments which act on a volume element $\bar{v}$ which is dx in length, are shown in Figure IV-3. At any depth x, T is the torque present. Summation of moments shows that:

$$T - (T + dT) + (\tau_{if}\ 2\pi R dx) \cdot R = 0$$

or

$$\frac{dT}{dx} = 2\pi R^2 \tau_{if} \tag{5}$$

Taking an arbitrary cross-section at any position x along the length of the rod shown in Figure IV-2, for the interfacial element ABCD shown in Figure IV-4 of "thickness" b_{if}, the shear strain within it, S_{if}, can be approximated by:

$$S_{if} = \frac{R\gamma}{b_{if}} \text{ (for } R/b_{if} >>1) \tag{6}$$

where γ is the twist angle at position x. τ_{if} and S_{if} are related by:

$$\tau_{if} = G_{if} S_{if} \tag{7}$$

where G_{if} is the interfacial shear modulus. Substitution of (6) into (7) and differentiation yields:

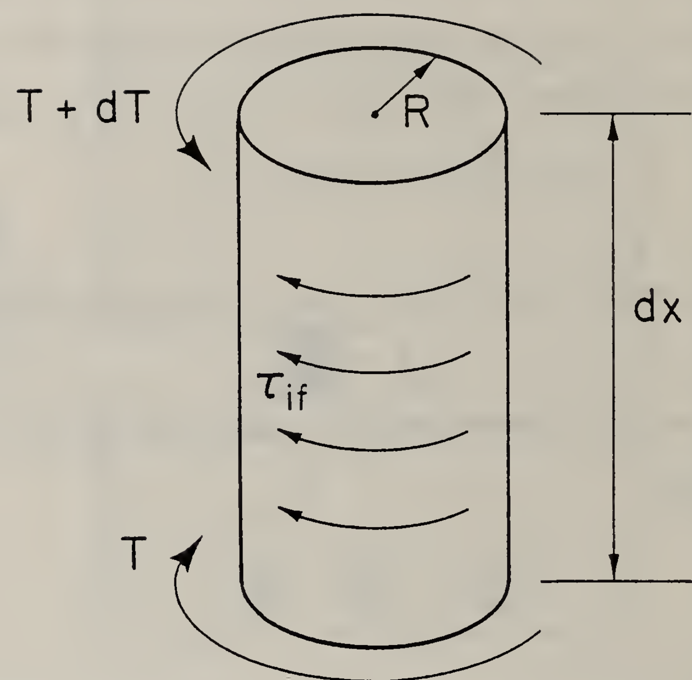
$$\frac{d\tau_{if}}{dx} = \frac{G_{if} R}{b_{if}} \frac{d\gamma}{dx}$$

for the axisymmetric case where τ_{if} and γ are independent of the angular position of element ABCD.

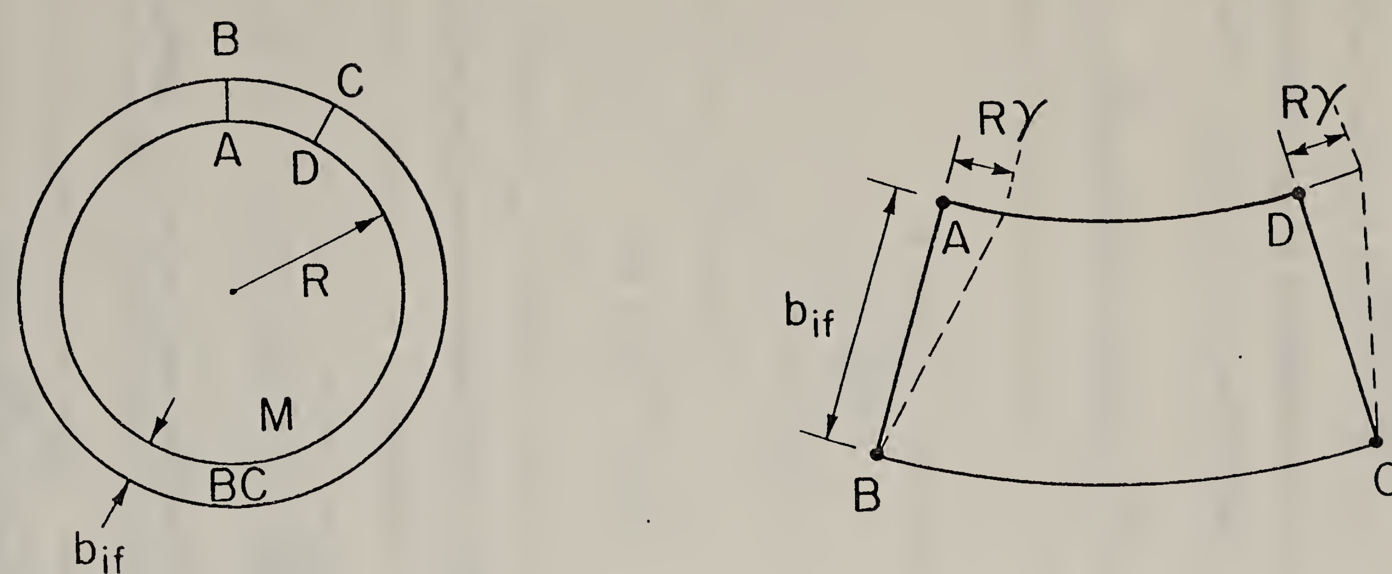
For volume element $\bar{v}$ shown in Figure IV-3 the twist angle gradient can be expressed according to the standard formula (Dieter, 1976):

$$\frac{T}{GJ} = \frac{d\gamma}{dx} \tag{8}$$

where G is the shear modulus of the metal and J is the polar moment of inertia of the rod ($\pi R^4/2$).



IV - 3 Torque T and Surface Shear Stress τ_{if} Acting on Volume Element $\bar{v}$ at Position x



IV - 4 Undeformed and Deformed Geometry for Interfacial Element
A B C D

Here $d\gamma$ is the difference in twist angle between the two cross sections of the ends of the volume element. By substitution of eq. (8) into eq. (7) the interfacial stress gradient can be seen to be:

$$\frac{d\tau_{if}}{dx} = \frac{G_{if}RT}{GJb_{if}} \qquad (9)$$

Differentiation of eq. (5) with respect to x and elimination of the stress gradient between this equation and eq. (9) yields:

$$\frac{d^2T}{dx^2} = \beta^2 T, \text{ where } \beta = [4G_{if}/Gb_{if}R]^{\frac{1}{2}} \qquad (10)$$

for which the solution is:

$$T = C_1 \sinh \beta x + C_2 \cosh \beta x \qquad (11)$$

For the boundary conditions:

$$T = T_{app} \text{ at } x = 0$$

$$T = 0 \quad \text{ at } x = L_{ac}$$

it can be shown that:

$$T = -T_{app} \coth \beta L_{ac} \sinh \beta x + T_{app} \cosh \beta x \qquad (12)$$

Differentiation of this equation with respect to x and substitution into eq. (5) yields τ_{if} as a function of position:

$$\tau_{if} = \frac{\beta T_{app}}{2\pi R^2} (- \coth \beta L_{ac} \cosh \beta x + \sinh \beta x) \qquad (13)$$

For an applied torque T_{app}, the maximum magnitude of τ_{if}, denoted τ_{if}^m, occurs at x = 0 and is equal to:

$$\tau_{if}^m = \frac{\beta T_{app}}{2\pi R^2} \coth \beta L_{ac} \qquad (14)$$

From torque versus twist angle experimental data, the torsional interfacial strength τ_{is} can be determined from eq. (14) by measurement of the maximum applied torque T^m once the value of β is known. All of the parameters in β except for G_{if} can be straightforwardly determined. b_{if} can be taken to be the surface roughness measured by profilometry (see Table III-1). The sample geometry and shear moduli of the components are known. An estimated value of G_{if} can be employed to find β, or the more rigorous procedure described below can be used.

The following procedure can be employed to find an appropriate β value. An average interfacial shear stress present when T^m is applied, $\bar{\tau}_{if}$, can be defined as:

$$\bar{\tau}_{if} = \frac{T^m}{2\pi R^2 L_{ac}} \tag{15}$$

Equation (14) can then be expressed as:

$$\frac{\tau_{is}}{\bar{\tau}_{if}} = \beta L_{ac} \coth \beta L_{ac} \tag{16}$$

where τ_{is}, the interfacial shear strength for a sample loaded in torsion, is the magnitude of the value of τ_{if} at $x = 0$ when T^m is applied.

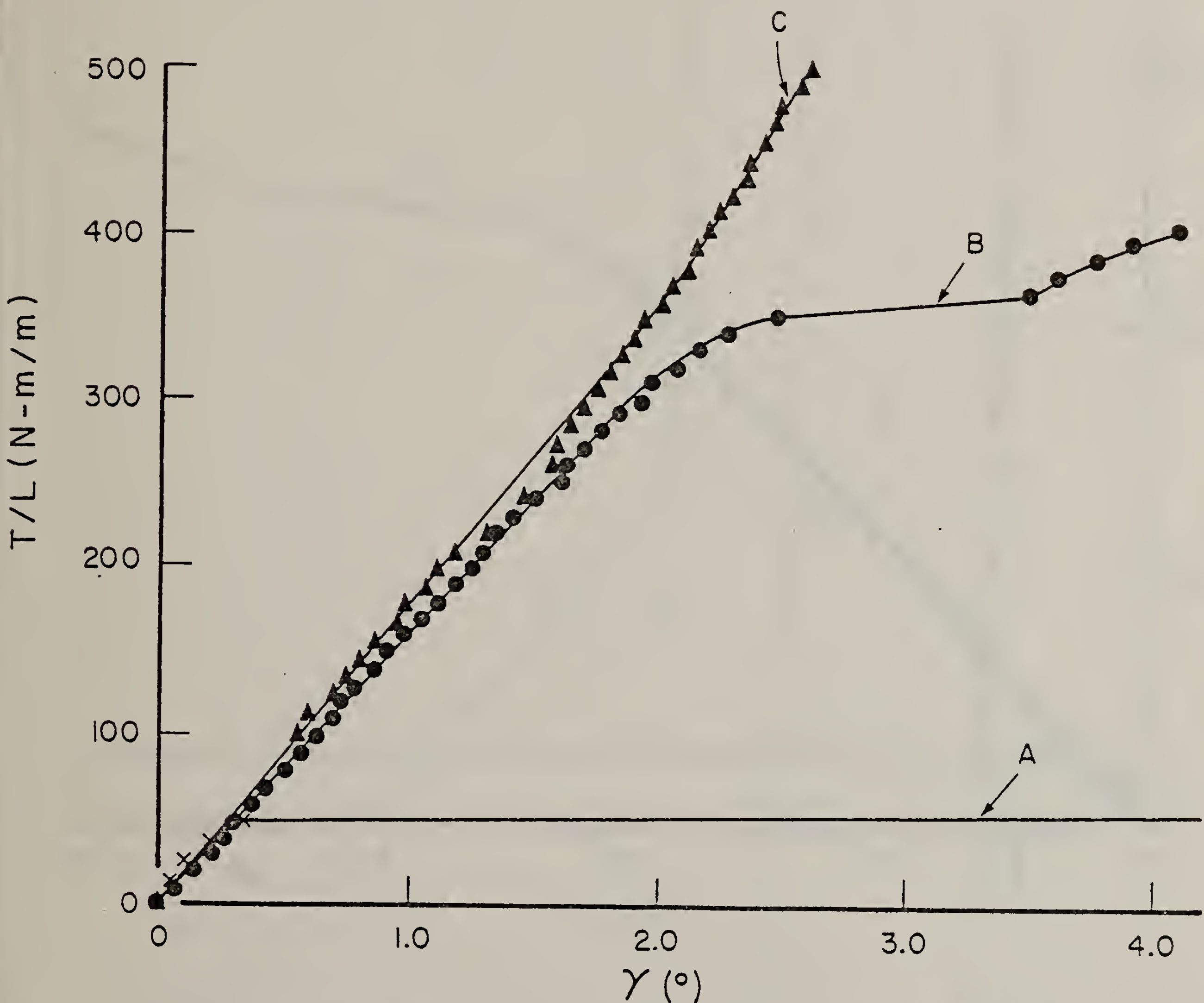
For a given metal surface and interface bond preparation procedure, β is a constant, so that the right hand side of eq. (16) is a function of length only. Hence, as $L_{ac} \to 0$, $\tau_{is}/\bar{\tau}_{if} \to 1$. Thus τ_{is} can be evaluated by measuring T^m in identically prepared specimens buried in acrylic to different depths and extrapolating $\bar{\tau}_{if}$ vs. L_{ac} data to zero length. Knowing τ_{is}, β can be determined from eq. (16) from one of the $\bar{\tau}_{if}$ (L_{ac}) measurements.

To illustrate these procedures the data obtained in last year's report is shown in Figure IV-5. Using $G_{if} = 10^3$ MPa (the modulus of the acrylic), the value used by Beaumont and Plumpton (1977) to analyze the results of push-out tests, the τ_{if}^{m} vs γ curves derived for interfaces A and B are shown in Figure IV-6. The values observed at yielding are about 230 MPa and 30 MPa respectively. The τ_{is} value determined by Beaumont and Plumpton for a stainless steel rod with a rougher surface finish than that used here was 18 ± 2 MPa. On the one hand, the differences between the two studies point out that the relatively high pressure technique does produce a higher quality interface than when techniques closer to the standard clinical methods are used. On the other hand, the extremely high τ_{is} value indicates that the G_{if} value used above is probably a substantial overestimate.

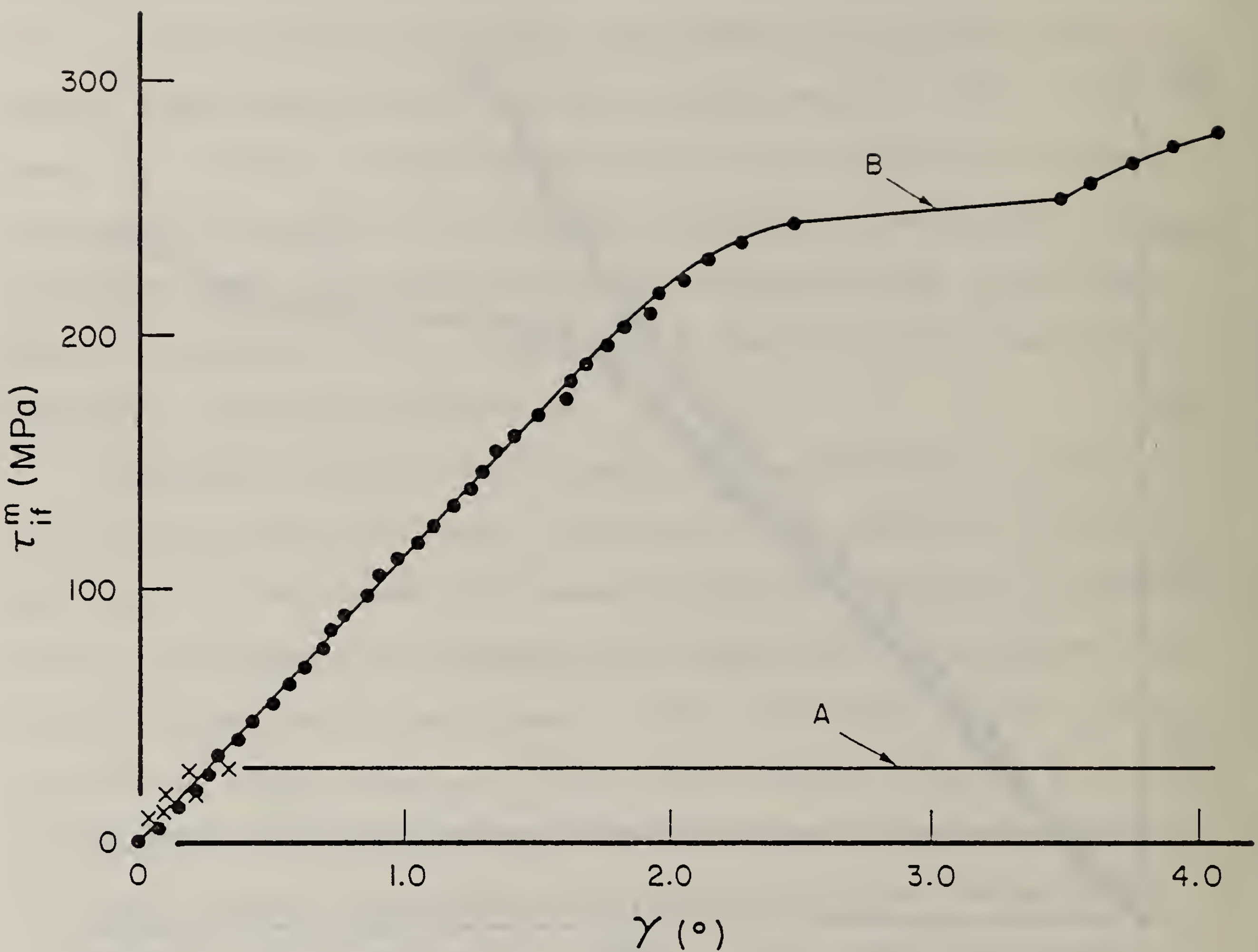
Accordingly, the more vigorous procedure described above for obtaining the correct β value was pursued. In this work 11 specimens of Ti-6Al-4V ELI polished to a 15μm diamond finish were prepared with a range of L_{ac} values. Previous experimental work (Beaumont and Plumpton, 1977) with push-out shear tests indicated that one would expect a horizontal plateau on the $\bar{\tau}_{if}$ vs. L_{ac} curve at the higher values of L_{ac} and a rather steeply increasing line as L_{ac} gets smaller. As is shown in Figure IV-7 this type of behavior was observed (with wide scatter) in the experimental data measured here. Below 2.5 cm elevated $\bar{\tau}_{if}$ values were seen. The regression line shown in the figure for the six data points with the lowest L_{ac} values (i.e. below 2.5 cm) is:

$$L_{ac} = 2.549 - 0.2047\ \bar{\tau}_{if}$$

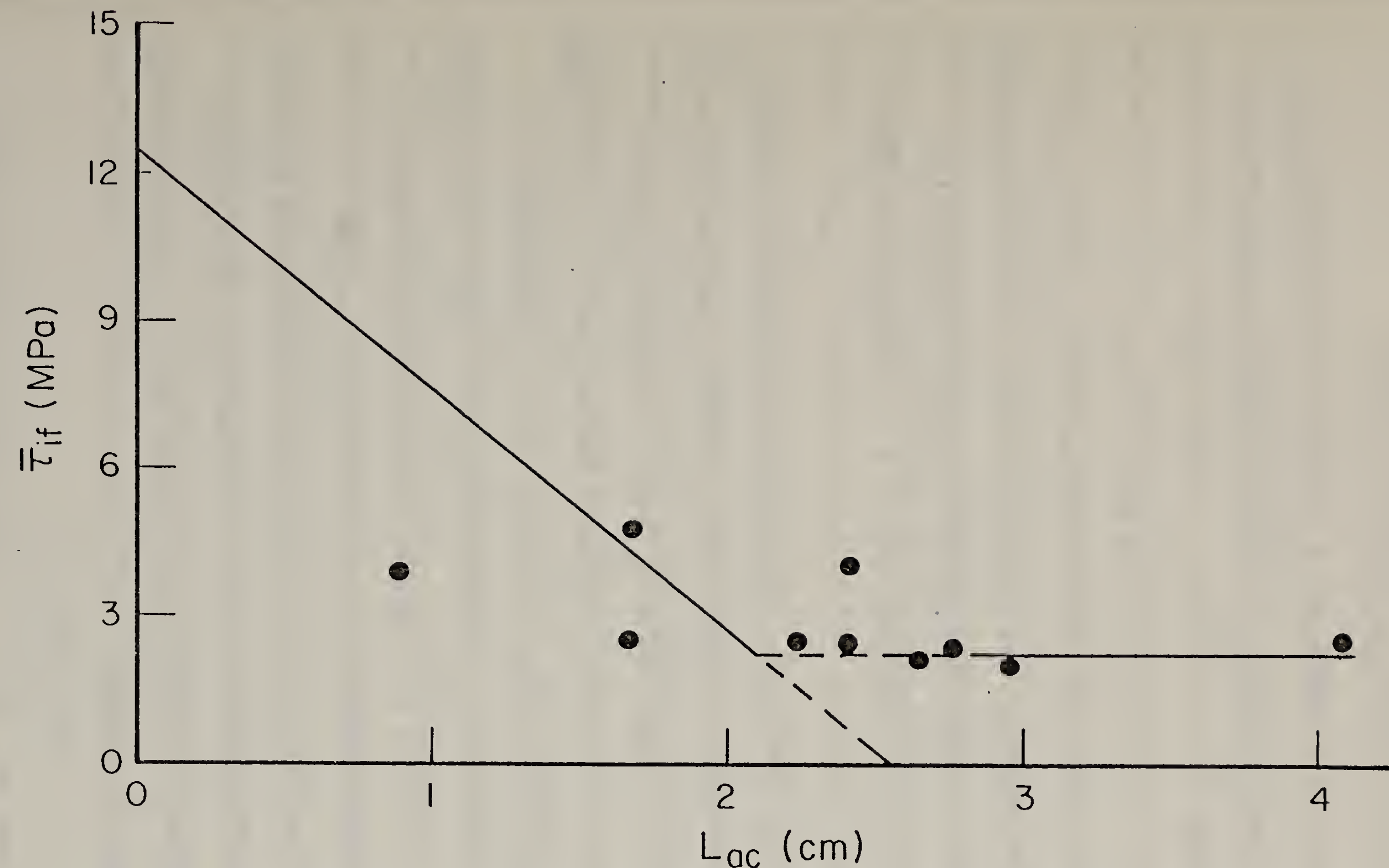
which corresponds to a τ_{is} value (i.e., $\bar{\tau}_{if}$ at $L_{ac} = 0$) of 12.45 MPa. The value that was determined by Beaumont and Plumpton for a stainless steel/PMMA interface was 18 ± 2 MPa. Due to the wide data point scatter, if the dependent and independent variables are interchanged in the regression, the τ_{is} value is 4.45 MPa.



IV - 5 Length-normalized Torque T/L_{ac} vs. Twist Angle γ for Interfaces, A, B, and C



IV - 6 Maximum Interfacial Shear Stress τ_{if}^{m} vs. Twist Angle γ



IV - 7 Average Interfacial Stress $\overline{\tau}_{if}$ at Maximum Torque vs. Acrylic Length L_{ac}

Solving equation (16) for β using the $\bar{\tau}_{if}$ value which falls closest to the regression line given in Figure IV-7 showed that:

$$\beta = 1.549 \text{ cm}^{-1}$$

Using the following values: $R = 0.3175$ cm, $b_{if} = 2.2 \times 10^{-5}$ cm (the measured roughness of 15μm T_i-6Al-4VELI), and $G_{Ti} = 3.85 \times 10^4$ MPa, interfacial shear modulus G_{if} was found to be:

$$G_{if} = 0.161 \text{ MPa}$$

Although strictly speaking, one cannot exclude the possibility that G_{if} will be different for different materials and surface finishes, it was not possible to measure $\bar{\tau}_{if}$ vs L_{ac} data for each combination individually (due to time constraints) so that this value of G_{if} was used in all calculation for the data in Chapters V and VI.

It should be emphasized that due to the uncertainties which are present in the calculation of interfacial strength, the τ_{is} values given in Chapters V and VI should be considered as approximate at least in comparison with the normalized torque. These uncertainties are due to imprecision in the measurement of surface roughness, data point scatter in the $\bar{\tau}_{if}$ vs. L_{ac} regression, and the assumption made above that the G_{if} value determined for 15μm Ti-TAl-4V ELI can be generally applied. At this point the τ_{is} values given in Chapters V and VI are not known precisely enough to be used for design purposes.

It is interesting to note that the G_{if} value above obtained from a torsion test is much lower than the value obtained for the interfacial shear modulus in the push-out test--1000 MPa (Beaumont and Plumpton, 1977). The significance, if any, of this discrepancy is uncertain.

CHAPTER V

INFLUENCE OF SURFACE FINISH AND MATERIALS ON THE TORSIONAL STRENGTH OF THE M/BC INTERFACE

The data which was obtained in this study is shown in tabular form in three appendices. Appendix 1 provides a complete list of the samples tested and describes, by sample number: the material, the surface finish, length of the acrylic block L_{ac}, whether or not sterilization or passivation was used, and the cure time. Special conditions for the test, such as whether an altered value of strain rate or the rigorous surface cleaning procedure was used, are given in the remarks column. Appendix 2 provides a listing by sample number of the mechanical properties of the interfaces which includes the normalized torque, T^m/L_{ac}, T^m itself, the calculated interfacial shear strength τ_{is}, β, γ_y (the twist angle at the yield point), an effective shear modulus $G_{eff} = T^m/\gamma_y$, and G_{eff}/L_{ac}. Appendix 3 provides a listing of the interfacial mechanical properties classified according to the material and surface condition which includes T^m, T^m/L_{ac}, τ_{is}, and G_{eff}/L_{ac}.

The sample set which is discussed in this chapter consists of those samples which were tested at the standard twist rate of 11.25°/sec, cleaned according to the ordinary procedures, and for which the cure time was four days or greater. Cure times less than four days are excluded here since this has an effect on mechanical properties as discussed in the next chapter. Only those samples which were not sterilized and passivated are considered here, the influence of these effects are considered in the next chapter. Thus only the influence of materials and surface finish are discussed in Chapter V.

Surface Finish

Table V-1 shows the mean value of T^m/L_{ac}, the number of samples measured N, and the observed range for the materials and finishes investigated.

TABLE V-1

NORMALIZED MAXIMUM TORQUE T^m/L_{ac} FOR M/BC INTERFACES FORMED FROM DIFFERENT MATERIALS WITH VARIOUS SURFACE FINISHES

FINISH

Material	N	1μm	N	6μm	N	15μm	N	Grit Blasted
316L	3	668* (225,758,1020)	3	297 (114,143,633)	5	148 (145,148, 149,150, 150)	3	562 (554,556,575)
Ti-6Al-4V-ELI	3	193 (174,202,205)	3	162 (133,171,182)	12	176 (123, 134, 138,146, 151, 151,152, 153,161, 245,252, 301)	4	298 (192,322,324, 354)
Co-Cr-Mo	3	419 (245,329,682)	3	218 (126,256,272)	3	185 (157,188 210)	2	391 (378,403)

*units: Newtons

mean value is not in parentheses

observed range of values in parentheses

Information for 316L, Ti-6Al-4V ELI, and the Co-Cr-Mo alloy with 1μm, 6μm, 15μm, and grit blasted finishes are given. Table V-2 shows the mean τ_{is}, number of specimens tested, and range. For visual clarity the mean values of T^m/L_{ac} and τ_{is} are shown in Figures V-1 and V-2.

There are several points to be noted from these figures. The most important one is that, contrary to what would be intuitively expected, these measures of the interfacial strength do not monotonically increase with a rougher surface finish. The T^m/L_{ac} curve shows a value at the finest surface finish (1μm) which is comparable to or exceeds that for the grit blasted finish and has a dip in the middle at the two intermediate finishes. The τ_{is} versus surface finish curve is fairly flat for the three coarser finishes and increases for the 1μm finish.

If this non-monotonic behavior were only observable in the τ_{is} curve, it might be suspected that it was caused by an artifact in the calculation due to the neglect, in the analysis described in Chapter IV, of some crucial factor which influences the strength. However, the normalized torque is a purely experimental quantity, whose value is not in any way based upon any assumptions made in a theoretical calculation. Thus, the higher value at 1μm is a true indication of a higher degree of "holding power" for a highly polished metal/acrylic interface. The fundamental reasons for this is not certain. Some discussion of possible mechanisms is found later in the report.

Another trend which was observed, at least for 316L and the Co-Cr-Mo alloy was that, for the two finest finishes (1μm and 6μm), greater scatter and less reproducibility was observed. Although, accurate statistical comparisons can not be made due to small sample sizes and differing numbers of samples tested, a rough measure would be the observed data range $\Delta\tau_{is}$ normalized to

TABLE V-2

INTERFACIAL SHEAR STRENGTH τ_{is} DETERMINED FROM TORSION TESTS ON M/BC

INTERFACES FORMED FROM DIFFERENT MATERIALS WITH VARIOUS SURFACE FINISHES

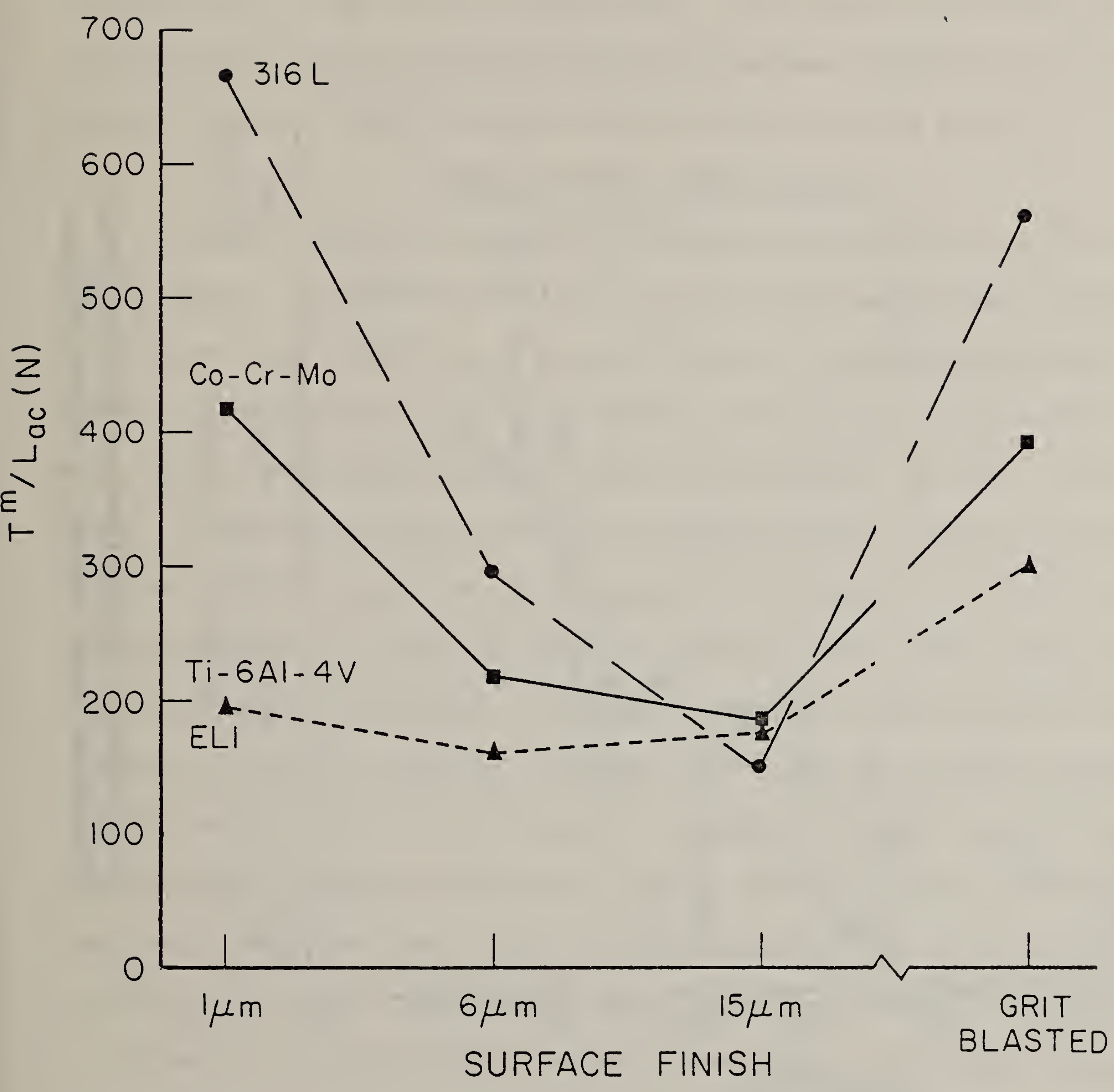
FINISH

Material	N	1μm	N	6μm	N	15μm	N	Grit Blasted
316L	3	33.3* (13.0,43.0,43.8)	3	14.0 (4.88,8.43,28.8)	5	6.65 (6.20,6.46,6.76, 6.82,6.94)	3	12.1 (12.0,12.1,12.3)
Ti-6Al-4V ELI	3	14.3 (12.7,14.3,15.8)	3	10.7 (7.62,10.3,14.3)	12	10.4 (6.17,6.60,8.65 9.33,9.34,9.35, 9.46,10.3,10.6, 13.1,15.6,16.9)	4	7.15 (3.97,7.74 8.16,8.72)
Co-Cr-Mo	3	21.4 (12.5,15.3,36.3)	3	11.9 (6.18,14.6,14.9)	3	8.63 (7.30,9.13,9.46)	2	8.10 (7.93,8.26)

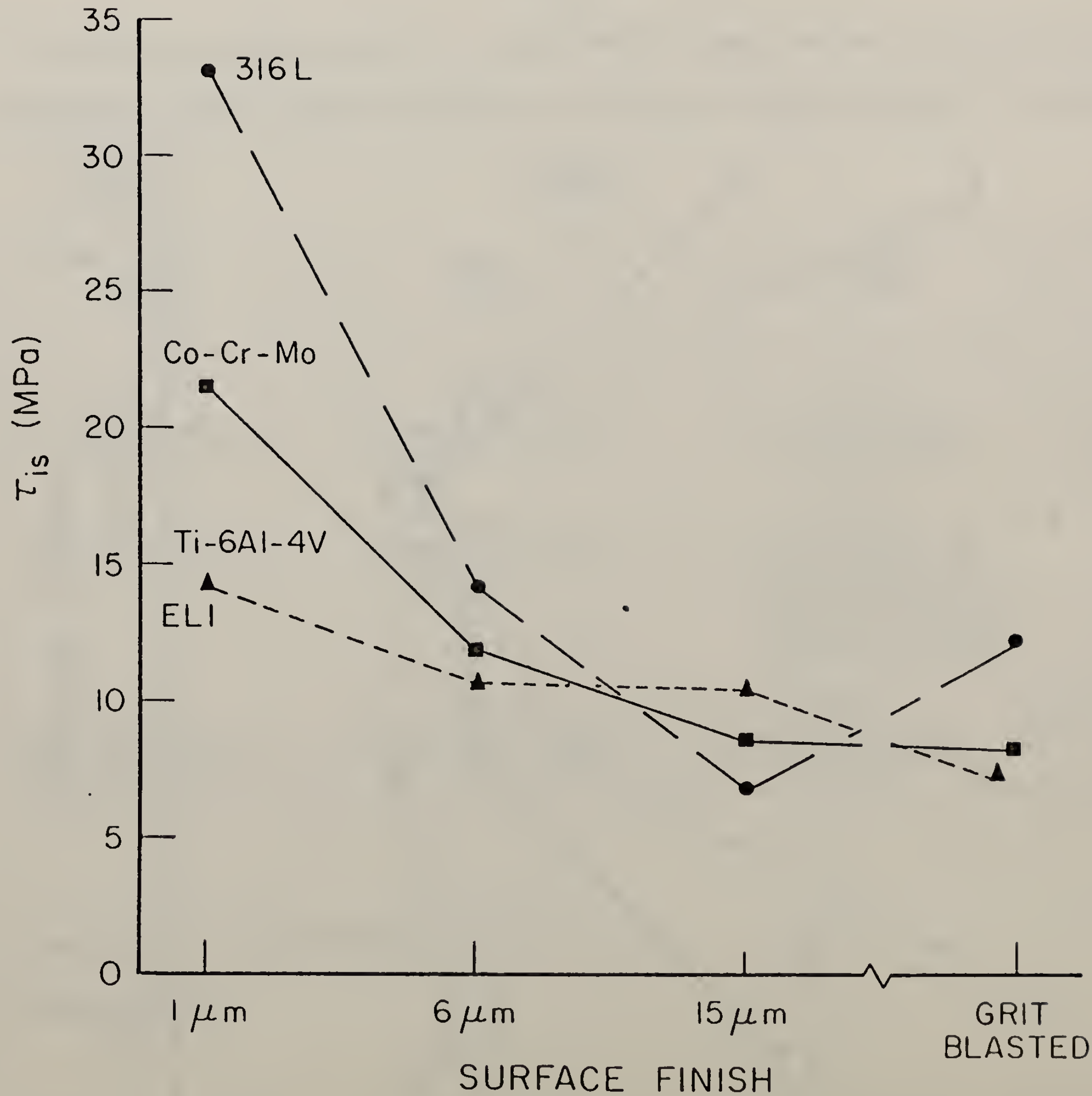
*Units: MPa

observed range of values given in parentheses

mean value is not in parentheses



V-1 The Influence of Surface Finish on the Mean Values of Normalized Maximum Torque T^m/L_{ac} for M/BC Interfaces



V-2 The Influence of Surface Finish on the Mean Values of Interfacial Shear Strength τ_{is} of M/BC Interfaces

the mean value of τ_{is} and number of samples tested. Table V-3 shows the values of $\Delta\tau_{is}/N\tau_{is}$ for the different materials and finishes. For the two coarsest finishes, this parameter is usually under 10%, whereas for the 1μm and 6μm finish it was typically above 20%. This is what intuitively would be expected due to the increased difficulty of specimen preparation and the greater care which must be taken to obtain a finer surface polish.

Comparison With Other Research

It is of interest to compare the data obtained here with that from other investigators. A precise comparison is not possible because each investigator or group of investigators has employed different experimental procedures. Tables V-4 through V-6 allow an approximate comparison to be made, however. They contain interfacial strength results from push-out, pull-out, and tension tests. Standard deviations are given for those studies in which they were obtained. Samples made from passivated metal surfaces are included in the tables, since as is indicated in the next chapter, passivation probably has little influence on interfacial strength. Information regarding the surface roughness, interface formation procedure, cure time, and interface formation time is given in Tables V-4 through V-6 to the extent that it is specified in the references. Some of the studies cited in these tables also include other test results acquired under conditions less comparable to the data determined in the present study. For brevity, these results are omitted from the tables.

There are several points to be noted when comparing the data obtained in the torsion tests reported here in Table V-2 with that in Tables V-4 through V-6. The first is with regard to reproducibility. For only three of the combinations given in Table V-2 were four or more specimens measured. Calculating standard deviations for these conditions it is seen that for 15μm 316L:

TABLE V-3

SCATTER OBSERVED IN INTERFACIAL STRENGTH FOR DIFFERENT MATERIALS WITH VARIOUS SURFACE FINISHES

$\Delta\tau_{is}/N\tau_{is}$

FINISH

Material	1μm	6μm	15μm	Grit Blasted
316L	30.9%	56.8%	2.23%	0.83%
Ti-6Al-4V ELI	7.40%	20.6%	7.51%	15.5%
Co-Cr-Mo	37.1%	24.5%	8.34%	2.04%

TABLE V-4

INTERFACIAL STRENGTH MEASUREMENTS OF Ti-6Al-4V
DETERMINED BY OTHER INVESTIGATORS

Test	Calculation Method	Interfacial Strength (MPa)	Roughness	Interface Formation Procedure	Remarks	Reference
Tension	Force Divided by Area	5.4 ± 0.8	0.1μm metallographic polish, subsequently electropolished and passivated	1 lb. applied for 1 minute with plunger	3 min IFT 1 day cure time	Keller et a
Tension	Force Divided by Area	8.3 ± 2.2	0.1μm metallographic polish, subsequently electropolished and passivated	1 lb. applied for 1 minute with plunger	3 min IFT 1 week cure time	Keller et a
Tension	Force Divided by Area	5.4 ± 2.0	15μm (metallographic polish)	1 lb. applied for 1 minute with plunger	3 min IFT 1 day cure time	Keller et a
Tension	Force Divided by Area	3.9 ± 2.0	15μm (metallographic polish)	1 lb. applied for 1 minute with plunger	3 min IFT 1 week cure time	Keller et a
Push-out	Maximum Interfacial Principal Stress (via FEA)	12.5 ± 1.8	1.9μm (probably via profilometry) sterilized and passivated	metal pushed into bone cement mass	1 day cure time	Raab et al.

TABLE V-5

INTERFACIAL STRENGTH MEASUREMENTS OF Co-Cr-Mo ALLOYS DETERMINED BY OTHER INVESTIGATORS

Test	Calculation Method	Interfacial Strength (MPa)	Roughness	Interface Formation Procedure	Remarks	Reference
Tension	Force Divided by Area	9.1 ± 1.5	0.1μm metallographic polish, subsequently electropolished and passivated	1 lb. applied for 1 minute with plunger	3 min IFT 1 day cure time	Keller et al.
Tension	Force Divided by Area	6.7 ± 1.2	0.1μm metallographic polish, subsequently electropolished and passivated	1 lb. applied for 1 minute with plunger	3 min IFT 1 week cure time	Keller et al.
Tension	Force Divided by Area	7.9 ± 1.4	15μm (metallographic polish)	1 lb. applied for 1 minute with plunger	3 min IFT 1 day cure time	Keller et al.
Tension	Force Divided by Area	6.7 ± 1.9	15μm (metallographic polish)	1 lb. applied for 1 minute with plunger	3 min IFT 1 week cure time	Keller et al.
Push-out	Maximum Interfacial Principal Stress (via FEA)	6.9 ± 0.7	1.1μm (probably via profilometry) sterilized & passivated	metal pushed into bone cement mass	1 day cure time	Raab et al.

TABLE V-6

INTERFACIAL STRENGTH MEASUREMENTS OF STAINLESS STEELS
DETERMINED BY OTHER INVESTIGATORS

Test	Method	Interfacial Strength (MPa)	Roughness	Interface Formation Procedure	Remarks	Reference
Push-out	Maximum Interfacial Principal Stress (via FEA)	11.2 ± 1.9	2.3μm (probably via profilometry), sterilized and passivated	metal pushed into bone cement mass	1 day cure time	Raab et al.
Push-out	Average Interfacial Shear Strength	1.35 ± 0.07	"polished"	injection by syringe into mold		Greenwald & Wilde
Push-out	Average Interfacial Shear Strength	9.2 ± 3	0.1-8μm CLA	packed tightly into a mold with the fingers	1 day cure time	Beaumont & Young
Pull-out	Maximum Interfacial Shear Stress (via shear-lag analysis)	18	3μm CLA	packed tightly into a mold with the fingers	1 day cure time $G_{if} = 10^3$ MPa	Beaumont & Plumpton
Tension	Force Divided by Area	11.0 ± 2.6	0.1μm (metallographic polish, electropolished & passivated)	1 lb. load applied for 1 min with plunger	3 min IFT 1 day cure time	Keller et al.
Tension	Force Divided by Area	9.2 ± 1.2	0.1μm (metallographic polish, electropolished & passivated)	1 lb. load applied for 1 min with plunger	3 min IFT 1 week cure time	Keller et al.
Tension	Force Divided by Area	6.3 ± 2.1	15μm (metallographic polish)	1 lb load applied for 1 min with plunger	3 min IFT 1 day cure time	Keller et al.
Tension	Force Divided by Area	10.9 ± 0.7	15μm (metallographic polish)	1 lb load applied for 1 min with plunger	3 min IFT 1 week cure time	Keller et al.

τ_{is} = 6.65 ± 0.305 MPa, for grit blasted Ti-6Al-4V ELI: τ_{is} = 7.15 ± 2.15 MPa, and for 15μm Ti-6Al-4V ELI: τ_{is} = 10.45 ± 3.25 MPa. The standard deviations expressed as percentages of the means are respectively 4.6%, 30.1%, and 31.5%. Although it is difficult to make a precise comparison, it appears that all of the tests described - push-out, pull-out, tension, and torsion have comparable reproducibility. This implies that, rather than being limited by the mechanical testing procedures, reproducibility of results is mainly governed by the ability to prepare the metal surface identically for each sample and to follow exactly the same interface formation procedure each time. There are probably practical and conceptual differences between these tests regarding their accuracy, however, which gives the torsion test a significant advantage. These aspects are discussed later.

Generally speaking, comparison of the data obtained here (in which the interface was formed by applying relatively high pressure to the interface as it was setting up) with that obtained by the other methods (in which relatively low pressure was applied) supports the hypothesis that a stronger interface is formed by the application of higher pressure. Comparison of the data in Table V-2 with that in Tables V-4 through V-6 indicates that in the vast majority of cases, independent of the surface roughness, the interfacial strength values from the high pressure interfaces are greater than those formed with low pressure techniques. Although there are a few exceptions and the comparison is blurred due to differences in loading mode, roughness, cure time, etc., nonetheless, the highest strength was almost always observed for the high pressure method. Also, the greatest value observed for interfaces formed using lower pressure very often barely exceeded the lowest value in the comparable material which had an interface formed with the high pressure technique. These

increased values due to high pressure probably indicate a higher true surface area of contact for the high pressure technique.

One apparent exception is the 18 MPa value for stainless steel/bone cement interfaces determined by Beaumont and Plumpton (1977) via shear-lag analysis of push-out tests assuming $G_{if} = 10^3$ MPa. For the 316L/BC interfaces given in Table V-2, the G_{if} value used was 0.161 MPa (determined as described in Chapter IV). If the values from the two studies are recomputed using comparable G_{if} values, then the lowest τ_{is} for an interface formed by applying high pressure is more than 20 times greater than the τ_{is} that Beaumont and Plumpton observed.

Two types of tests provided some support for the hypothesis that the high pressure interface formation technique did produce a greater degree of contact between the metal and the acrylic. With two samples, one hour prior to the test saline solution was put on the top surface of the acrylic block. If there were a significant degree of porosity at the interface (as is probably the case in the clinical situation) one would expect fluid infiltration along the M/BC interfaces of these samples due to capillarity. Since it has been observed (Beaumont and Young, 1977) that M/BC interfaces where water is present are weaker than dry interfaces, it would be expected that the samples in this study exposed to saline would be weaker than comparable interfaces tested dry if there had been fluid infiltration due to porosity. However, these samples had mechanical properties well within the range observed on dry samples.

Also, in two other specimens due to errors committed during the interface formation, the acrylic was poorly placed and contained irregularities and gaps. These M/BC interfaces were more similar to the clinical situation. During mechanical testing they proved to be significantly weaker than their counterparts which had been formed with the high pressure technique without any flaws in procedure.

Differences Between Materials

A final consideration is concerned with differences between materials. There seems to be differences between materials when test results are compared for the same surface finishes. The effect is most clear for the normalized torque data of Table V-1. For the 1μm, 6μm, and grit blasted finishes the metal/bone cement interfaces rank from strongest to weakest as: 316L, Co-Cr-Mo, and Ti-6Al-4V ELI. For the 15μm finish this ranking does not hold and the materials are rather similar (less than ±15% difference). With respect to interfacial shear strength, the 15μm values seem anomolously ranked also as can be seen by examination of Table V-2. τ_{is} otherwise seems to be larger for 316L than for the other materials. For Co-Cr-Mo and Ti-6Al-4V ELI the strengths are similar except for the 1μm finish for which the Co-Cr-Mo alloy has a higher interfacial shear strength.

Although not enough measurements were taken at all surface finishes to be certain, the data for sterilized and passivated alloys which had 1μm and 15μm surface finishes which is described in Chapter VI does not show clear differences in mechanical properties between materials.

Two studies by other groups of investigators have been conducted in which M/BC interfacial strength has been determined for different materials under comparable conditions of roughness and testing procedure (Raab et al., 1981), (Keller et al., 1980). The results are summarized in Table V-4 through V-6. Like the present study, each of these studies indicated that differences in τ_{is} between materials can be observed. Keller et al.'s data shows that τ_{is} changes with cure time between a one day and a one week period and that relative rankings of the materials change as well. Further work in this study described in Chapter VI shows that for cure times of 4 days or longer little change in τ_{is} occurs. Thus, comparisons of the ranking of materials determined from the

measurements of Raab et al. and Keller et al. (which have a one day cure time) with the results of the present study cannot be made.

The one week data of Keller et al. is comparable in a certain sense, but differences in ranking between materials for that study and the present one could simply reflect the fact that the different materials behave differently for tensile and torsional loading of the interfaces. Keller et al.'s study is consistent with the observation made here that different surface finishes can produce different rankings of materials.

Thus, in summary, it appears that differences do exist between the strengths of interfacial bonds for different materials which depend upon surface roughness and loading mode. Care must be taken when comparing results of different researchers to be sure all data was obtained after equivalent cure times. Although differences between materials do exist, at this point it cannot be determined in an overall sense which type of metal is preferable for preserving the mechanical integrity of the metal/bone cement interface in total hip replacements. Further analysis of interfacial stresses in actual devices subjected to physiological loading and further series of tests on M/BC interfaces in which only the loading mode differed would have to be conducted before this point could be conclusively resolved.

CHAPTER VI

OTHER FACTORS WHICH AFFECT INTERFACIAL STRENGTH PROPERTIES

Influence of Surface Pretreatment

A number of samples with 1μm and 15μm finishes were subjected to passivation and sterilization treatments typical of those used for surgical implants before interface formation. Otherwise, the metal/bone cement interfaces were prepared and tested in the same manner as were those discussed in Chapter V. A comparison of the mean values of normalized torque and interfacial shear strength measurements for the passivated and sterilized specimens, (termed the "pretreated" specimens) and the non-pretreated specimens are shown in Tables VI-1 and VI-2. For the pre-treated specimens the ranges are also given in the tables.

For the 15μm finish there appears to be little difference for any material in the interfacial mechanical properties caused by the pre-treatment. There may be a counter productive effect at 1μm of sterilization and passivation at least for 316L and Co-Cr-Mo. The statistical significance of this finding is doubtful, however. Table VI-3 shows the confidence levels of t-tests which tested the hypothesis that the mean value of the treated and untreated samples are different. If the 95% confidence level is taken to be the level considered to be significant, then no differences due to sterilization and passivation were observed.

The data in Table VI-2 gives some indication that sterilization and passivation treatments reduce the scatter in torsional measurements of interfacial shear strength. This was observed where the scatter for non-pretreated samples was large (316L and Co-Cr-Mo with a 1μm finish). Apparently the pretreatment produces a more uniform surface in these cases. For the other cases examined,

TABLE VI-1

COMPARISON OF THE NORMALIZED MAXIMUM TORQUE FOR PASSIVATED AND STERILIZED SPECIMENS WITH THAT FOR UNTREATED SPECIMENS

	Surface Finish			
Material and Condition	N	1μm Mean (Range)	N	15μm Mean (Range)
316L npt *		668 N		148 N
pt**	2	218 (199-237)	3	186 (147-263)
Ti-6Al-4V ELI npt		193		176
pt	2	166 (164-168)	2	173 (139-206)
Co-Cr-Mo npt		419		185
pt	2	178 (163-193)	2	152 (142-162)

*non-pretreated

**pre-treated

TABLE VI-2

COMPARISON OF MEAN INTERFACIAL SHEAR STRENGTH AND DATA POINT SCATTER FOR PASSIVATED AND STERILIZED SPECIMENS WITH THAT FOR UNTREATED SPECIMENS

	Surface Finish					
	1μm			15μm		
Material and Condition	N	Mean (Range)	$\Delta\tau_{is}/N\bar{\tau}_{is}$ (%)	N	Mean (Range)	$\Delta\tau_{is}/N\bar{\tau}_{is}$ (%)
316L npt*		33.3 MPa	30.9		6.65 MPa	2.23
pt**	2	12.6 (12.4-12.8)	1.67	3	7.18 (6.60-7.80)	5.57
Ti-6Al-4V ELI						
npt		14.3	7.40		10.4	7.51
pt	2	13.8 (13.0-14.7)	6.32	2	8.62 (7.82-9.42)	9.28
Co-Cr-Mo						
npt		21.4	37.1		8.63	8.34
pt	2	10.5 (10.5-10.5)	0.00	2	6.66 (5.57-7.75)	16.4

* non-pretreated

** pretreated

TABLE VI-3

CONFIDENCE LEVELS OF t-TEST COMPARISONS FOR DIFFERENCES IN INTERFACIAL SHEAR STRENGTH DUE TO PASSIVATION AND STERILIZATION

Material	Finish	Confidence level (C.1)
316L	1μm	90% < C.1. < 95%
316L	15μm	90% < C.1. < 95%
Ti-6Al-4V ELI	1μm	70% < C.1. < 80%
Ti-6Al-4V ELI	15μm	80% < C.1. < 90%
Co-Cr-Mo	1μm	80% < C.1. < 90%
Co-Cr-Mo	15μm	80% < C.1. < 90%

scatter in the non-pretreated samples was not particularly large and the passivation and sterilization produced little change. Presumably, here the surfaces were fairly uniform to begin with and thus pre-treatment offered little advantage with respect to reduced data point scatter.

In the study by Keller et al. (1980), it was reported that the tensile bond strength of M/BC interfaces prepared from metal polished to a 0.1μm finish and then electropolished and passivated exceeded that of interfaces prepared from metal which was polished to 15μm and not given these treatments. This finding is consistent with what has been observed in our study. The work described in this report allows a correct interpretation of these results to be made - i.e., that it is the influence of the finer surface finish and not the passivation treatment which is responsible for these differences.

Influence of Strain Rate

Although it was not at all a primary area of emphasis for this year's activities, a very preliminary investigation was made of the effect of twist rate on the mechanical properties of M/BC interfaces tested in torsion. Some effect would be expected because of the viscoelastic nature of the PMMA component.

Two 316L specimens were tested at twist rates of 2.81°/sec. and 50°/sec. which are slower and faster respectively than the rates normally used for these tests - 11.25°/sec. The surface finish was 15μm and the samples were otherwise prepared identically to those for which the data appeared in Tables V-1 and V-2. The test results were quite unexpected. The interfacial shear strength, normalized torque, and normalized effective shear modulus are shown in Table VI-4 for the three twist rates. The interfaces tested at the slow speed and the rapid speed were both much stronger (by a factor of 3-4) than

TABLE VI-4

INFLUENCE OF STRAIN RATE ON THE MECHANICAL PROPERTIES OF 316L/BC INTERFACES

Twist Rate	τ_{is}(MPa)	T^m/L_{ac}(N)	G_{eff}/L_{ac}(N/degree)
2.81°/sec	25.9	680	120
11.25°/sec	6.65 (6.20-6.94)	148 (145-150)	101 (64.4-122)
50°/sec	20.5	420	82.3

those tested at 11.25°/sec. The shear modulus behavior was anomolous and seemed to increase with decreasing twist rate which is the opposite of what would be expected from any linearly viscoelastic rheological model.

Since the effect of strain rate on interfacial strength would be important for implant performance and the effect on shear modulus would be of interest from the fundamental point of view (if the effects above can be confirmed in further tests), a priority area for future research is a study of the influence of strain rate on the properties of metal/bone cement interfaces.

Influence of Rigorous Cleaning

Since the ability of two surfaces to adhere can be strongly influenced by surface contaminants, it seems possible that interfacial bond strengths could be improved by following a rigorous cleaning procedure. Two Ti-6Al-4V ELI samples with 15μm surface finishes were subjected to the cleaning process described in Chapter III as a very preliminary investigation of this possibility. Otherwise, the samples were prepared and tested in the same manner as those discussed in Chapter V for which the mean values of τ_{is} and T^m/L_{ac} were 10.45 MPa and 175.7 N respectively.

The mean values of these parameters for the rigorously cleaned samples were 12.84 MPa (range: 12.19 and 13.50) and 224.5 (range: 191.4 and 257.5) which are, respectively 23% and 28% higher than those obtained with regular cleaning procedures. This result suggests that rigorous attention to cleaning procedures may be a way to increase bond strengths of pre-formed implant/bone cement interfaces although too few tests were performed this year to accurately assess this possibility. This effect should be investigated further in the future.

Influence of Cure Time

In a previous study (Keller et al., 1980) it was noted that M/BC interfaces tested in tension showed different strength levels when tested after cure times of one hour, one day, and one week. A portion of the results were given in Tables V-4 through V-6.

Nine samples used in this study were tested after a cure time of two days. Normalized torque values are shown in Table VI-5. For comparison purposes the means and ranges for samples tested at cure times t_c which were greater than two days are given. The t_c values are also listed. For 15μm surfaces some materials showed greater interface strength at two days and some showed less compared to the larger cure times. For Co-Cr-Mo the effect was different for treated and untreated samples. With the 15μm surfaces the differences with respect to cure time was substantial, and the specimens tested at two days never fell anywhere in the range of values observed at greater cure times. A similar effect was not apparent for 1μm finishes, perhaps because these show a larger data scatter.

Comparison of the one day and seven day results of Keller et al. (1980) with these two day and four day or longer t_c data do not always show consistent trends for a given material with respect to the magnitude and even the direction of change of interface strength caused by cure time. However, this is not surprising since the actual times, mode of loading (tension versus torsion), and surface finishes and treatments were different.

The point to be made from these observations, however, is that the cure time does seem to influence test results at least for cure times which are less than or equal to two days. Almost all of the tests conducted here were performed after 5-7 days of curing. It seems to be a prudent course of action to avoid M/BC interface testing at cure times which are shorter than this time period.

TABLE VI-5

INFLUENCE OF CURE TIME t_c ON THE NORMALIZED MAXIMUM TORQUE OBSERVED DURING TORSION TESTING OF M/BC INTERFACES

Material	Finish	Condition	T^m/L_{ac}(N) (t_c=2 days)	T^m/L_{ac}(N) (t_c>2 days)	t_c (days) (for t_c>2 days
316L	15μm	npt*	395	148** (145-150)***	4, 5, 19 (5 samples total)
Co-Cr-Mo	15μm	npt	444	185 (157-210)	5 (3 samples total)
Co-Cr-Mo	15μm	pt*	113	152 (142-162)	5 (2 samples total)
Ti-6Al-4V ELI	15μm	pt	91.4	173 (139-206)	5, 6 (2 samples total)
316L****	15μm	npt	677	420	5
316L	1μm	npt	247	668 (225-1020)	5, 6 (3 samples total)
Ti-6Al-4V ELI	1μm	npt	180	193 (174-205)	5, 6, 7 (3 samples total)
Co-Cr-Mo	1μm	npt	384 (279-488) (2 samples total)	419 (245-682)	5, 6 (3 samples total)

*npt: non-pretreated

pt: pretreated

**mean value is not in parentheses

***observed range of values in parentheses

****test was conducted at $\dot{\gamma}$ = 50°/sec

CHAPTER VII

DISCUSSION, SUMMARY, AND CONCLUSIONS

Discussion

There are a number of points which have been raised by the experiments conducted here which should be discussed further. The first of these concerns the accuracy of the different testing techniques. It appears that reproducibility of a given M/BC interface strength measurement is determined, as previously described, by the surface preparation and interface formation technique rather than the test method. Distinctions between methods can, however, still be made.

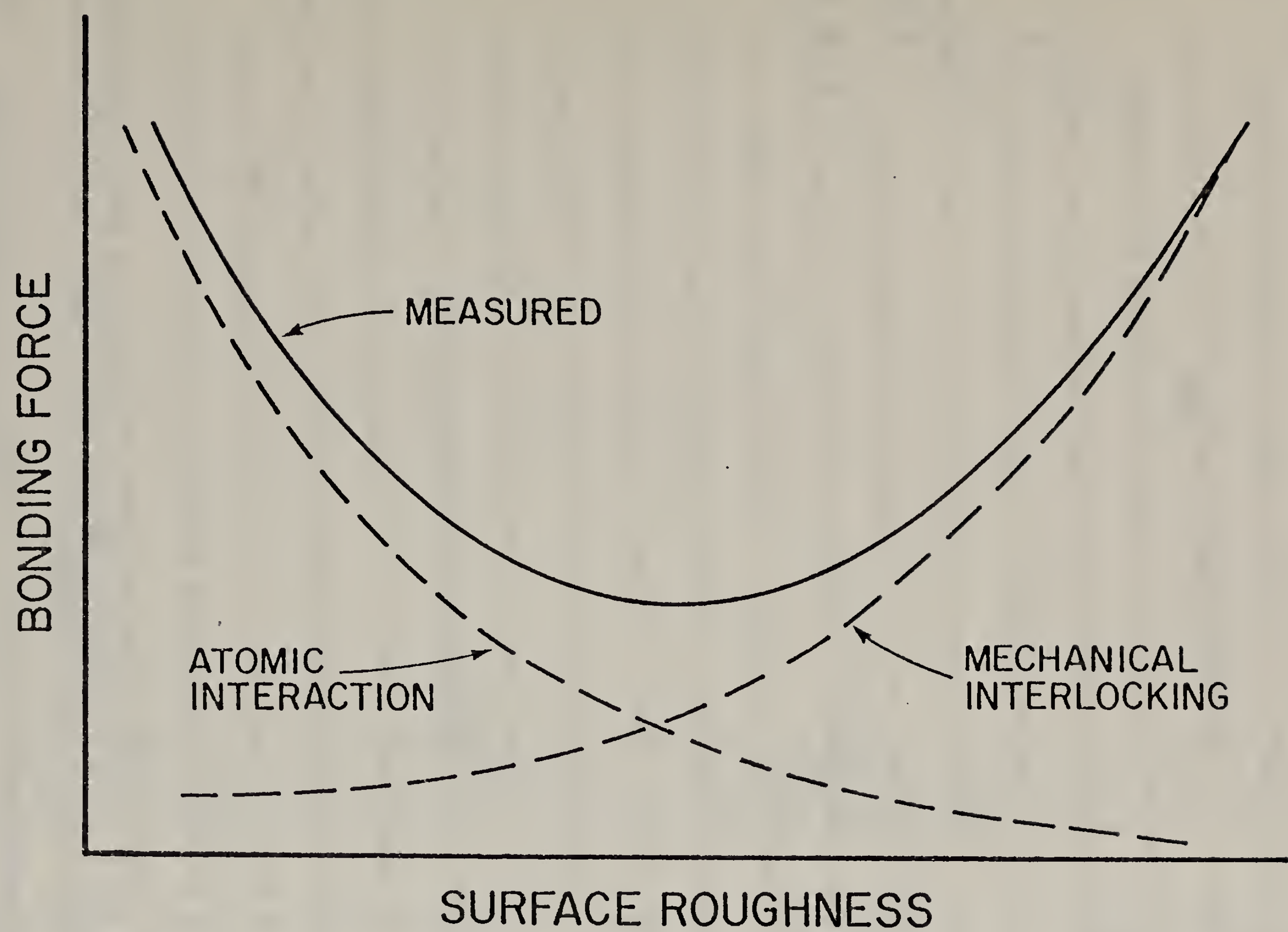
In tension measurements, for example, the fracture which is produced will propagate both at the interface and through the acrylic (Keller et al., 1980), (Raab et al., 1981), which leads to difficulty in interpreting the results in terms of the properties of the bond itself. This problem does not occur for the torsion specimen used here. For the push-out type shear tests, significant components of both shear and normal stresses are present at the interface (Raab et al., 1981) which can make precise identification of the failure mode difficult. It is thought that the torsion test gives a more unambiguous measurement of interfacial shear strength because it is possibly less influenced by normal stress components than is the push out or pull out test. Further improvement of the test described here could perhaps be obtained by applying torque to both ends of the rod simultaneously to generate a more even stress distribution.

Another interesting point is concerned with a mechanism for the observed variation of interfacial strength with surface roughness. It seems intuitively clear that a roughened, grit blasted surface into which the acrylic infiltrates

will be strengthened to an extent limited by the shear strength of the bone cement itself and the cross-sectional area of the interface which is occupied by acrylic. As the surface becomes smoother one would expect this mechanism to become less effective and for interfacial strength to decline. Up to a point, this is consistent with experimental observation.

The finest surface finish (1μm), however, was also quite strong and either comparable to or in excess of the strength for grit blasted material, which indicates that an additional mechanism is involved which influences interfacial strength and increases it when the metal has a very fine surface finish. Among the possible effects involved are an increased electrostatic interaction between the metal and bone cement (similar to the adhesion between two highly polished optical flats placed in contact due to the enhanced proximity of the surfaces), a difference in the amount of trapped air or surface "porosity" present at the interface which creates contact area differences, and size differences of interfacial flaws and voids from which the interfacial fracture would originate. At present the mechanism cannot be determined. Further attention should be paid to this matter because additional understanding of the factors which influence interface bonding could lead to strength improvements of M/BC interfaces.

With respect to the mechanism of adhesion between the metal and bone cement it is possible that the situation could be as indicated in Figure VII-1. The figure illustrates the idea that two components comprise the bonding forces between the surfaces. One is a force due to mechanical interlocking which is negligible for fine surface finishes and dominates for coarse finishes. The other force is an atomic (or chemical) interaction which dominates at fine surface finishes due to the proximity of the surfaces and which is negligible for coarse finishes. To some extent the normalized torque and

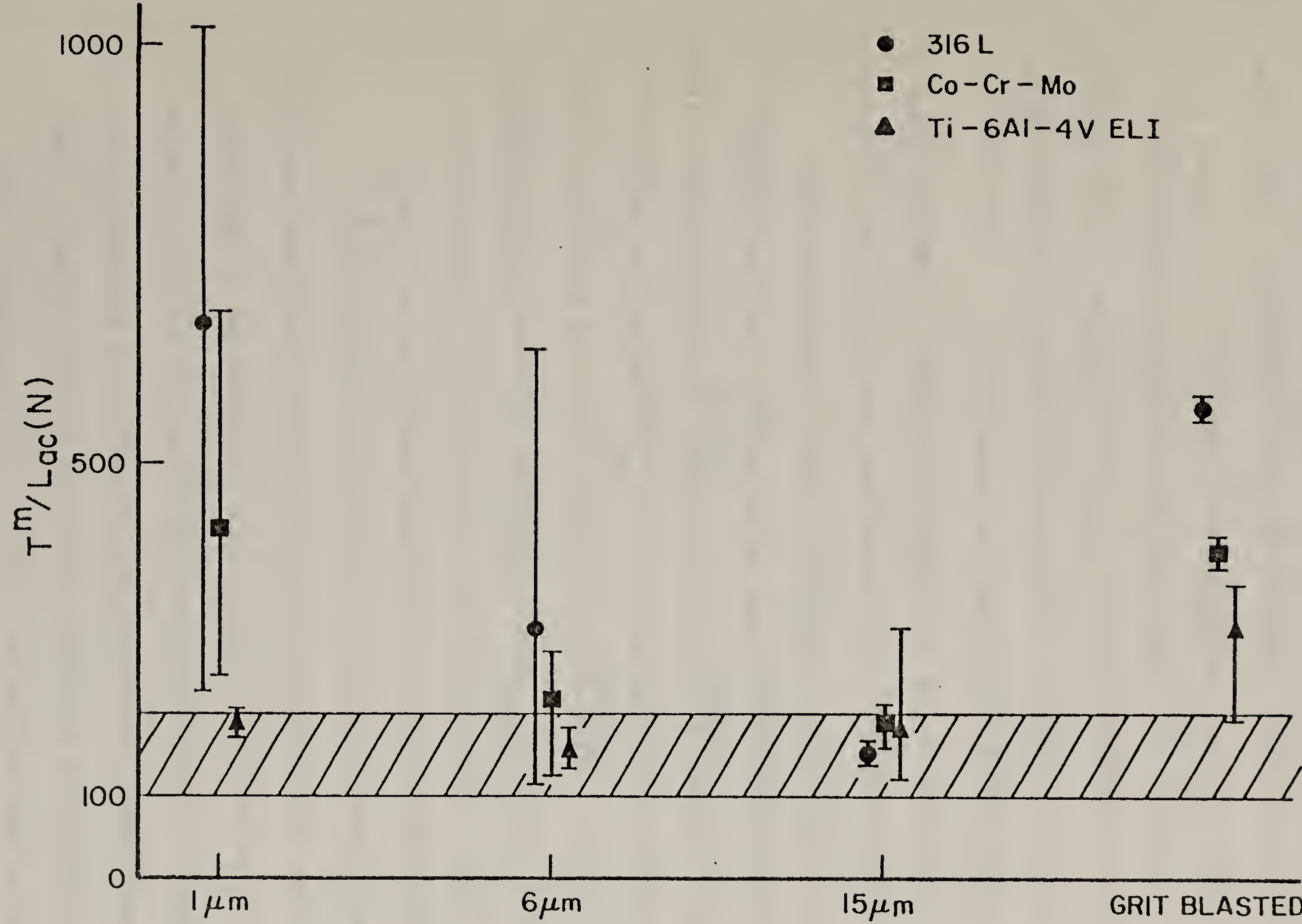


VII-1 Hypothetical Components of the Bonding Force Between Metal and Bone Cement Surfaces.

interfacial shear strength versus surface roughness data which was given in Figures V-1 and V-2 is consistent with the notion shown in Figure VII-1.

Figure VII-2 shows this correspondence more clearly. The data points shown by symbols in this figure are the mean values for normalized torque which appear in Figure V-1. The error bars associated with these points do not give the standard deviations but rather show the maximum and minimum values which were measured. The cross-hatched band between 100 and 200 N is where the vast majority of the measurements at the intermediate surface finishes were located. Except for one outlying point, all of the grit blasted samples were well above the band which indicates the influence of the mechanical interlock and the great reliability with which this type of surface can be used to strengthen M/BC interfaces. The dominance of the atomic (or chemical) force is seen at the finer surface finishes for the Co-Cr-Mo alloy and the 316L stainless steel. The titanium alloy shows little tendancy for atomic interaction. For the other two alloys at a 1μm finish both the mean and maximum values are well above the cross-hatched band. The atomic interaction effect can also be seen at 6μm for the maximum values. However, it appears that even with apparently identical surface preparation techniques, we were not able to assure that conditions were favorable in all samples to achieve the maximum degree of atomic interaction. At least one specimen with a weak bond (in or very near to the cross-hatched band) was observed for Co-Cr-Mo and 316L at 1μm and 6μm. Very likely there are other variables (as yet unidentified) which effect the performance of these specimens.

There is another point which should be considered with respect to the adhesion mechanism between the metal and bone cement. In addition to the roughness of the surface per se, the manner in which that surface is produced could be important. For example, subsurface effects which occur during fabrication, such as the layer of "disturbed metal" associated with polishing



VII-2 The Influence of Surface Roughness on the Mean and Extreme Values of Normalized Maximum Torque T^m/L_{ac} for M/BC Interfaces.

or compressive residual stresses associated with grit blasting, might be relevent since reactivity and oxide-forming tendency can be increased or decreased by coldwork.

The emphasis of this year's research has been to determine, within time and effort constraints, the main variables which influence the strength of M/BC interfaces in torsion. The thrust has been to study the effect of a number of different factors which possibly could be important, rather than to focus upon the statistical design of the sample set tested to achieve precise insight into the magnitude of the differences observed.

Some statistical calculations have been done however, to examine the two main theses which have emerged from the experiments which have been conducted, i.e., that 1) the finest surface (1μm) has a higher interfacial shear strength than the others which have been tested and 2) that the coarsest surface finish (grit blasted) and the finest surface finish have higher values of interfacial "holding power", measured as T^m/L_{ac}, than the intermediate finishes. Specifically, t-tests were performed to test the hypotheses that the mean values of τ_{is} and T^m/L_{ac} observed for the different surface finishes were greater than the minimum measured mean value (min.). The results are shown in Table VII-1 which gives the confidence levels for the t-test comparisons for the different materials and surface finishes studied.

These results are for the most part consistent with the theses mentioned above even though, a priori, the sample set was not designed to test their validity. For example, the normalized maximum torque for the grit blasted specimens is elevated above the minimum mean value for all materials to a highly significant degree (at confidence levels of 97.5% or higher). The elevation, although evident at the 1μm finish, is not as marked in the statistical sense. This would be expected based upon the discussion above

Table VII-1

Confidence Levels of t-Test Comparisons for Differences in Interfacial Strength and Normalized Maximum Torque Due to Surface Finish

$\underline{\tau_{is}}$

Hypothesis	316L	Ti-6Aℓ-4VELI	Co-Cr-Mo
1μm > min.	90-95%	99.5-99.9%	80-90%
6μm > min.	70-80%	80-90%	80-90%
15μm > min.	--	97.5-99%	70-80%
Grit-Blasted > min.	c.ℓ. > 99.95%	---	---

$\underline{T^m/L_{ac}}$

Hypothesis	316L	Ti-6Aℓ-4V ELI	Co-Cr-Mo
1μm > min.	90-95%	80-90%	80-90%
6μm > min.	70-80%	---	70-80%
15μm > min.	---	70-80%	---
Grit Blasted > min.	c.ℓ. > 99.95%	97.5-99%	c.ℓ. > 99.95%

regarding the scatter and the inability to consistly prepare the surface in an optimum fashion for the 1μm samples to maximize interfacial strength. The two intermediate finishes, 6μm and 15μm, show little evidence of statistically significant elevation above the minimum mean values (confidence levels were under 80%).

For the mean values of interfacial strength, the 1μm finishes do exhibit significant elevations above the minimum mean value (confidence levels between 80% and 99.9%). The data for the interfacial shear strength shown in Table VII-1 is interesting in that there appear to be differences in observed mean values which are highly statistically significant (e.g. for 15μm and 1μm Ti-6Aℓ-4V ELI compared to a grit blasted surface) but which actually would represent less improvement of interfacial strength above the minimum condition (percentage wise) than do finishes for other materials for which the degree of statistical significance was less. This can be seen by comparing the mean values in Table V-2 with the t-test results in Table VII-1.

Summary and Conclusions

Seventy-seven M/BC interfaces were formed using a relatively high pressure technique and tested in torsion to obtain torque versus twist angle data. Interfacial yielding was easily observed. An interfacial shear strength was calculated from the maximum measured torque and the sample geometry using a mathematical analysis based on shear-lag theory. Some profilometric measurements of the surface roughness were also obtained.

The main variables which were examined in this study were: 1) differences between materials (316L stainless steel, Ti-6Al-4V ELI, and a Co-Cr-Mo alloy were examined); 2) differences due to surface finish (grit blasted surfaces and surfaces polished with diamond paste down to 15μm, 6μm, and 1μm were employed); 3) the influence of sterilization and passivation treatments, and 4) the influence of cure time. A few preliminary tests involving rigorous cleaning procedures and different twist rates were also performed.

Few statistical analyses have been given in this report. The emphasis has been to study a fair number of different effects with a few samples each in order to isolate the main effects and variables which influence the test method and/or could be used to improve the interfacial strength rather than to obtain precise statistical information for a smaller number of effects. Further studies to get good statistics for the most important findings would be useful in the future.

The most important findings of this study are as follows:

1. Contrary to what would intuitively be expected, interfacial strength as assessed by the measured maximum normalized torque was greatest for the coarsest and for the finest surface finish as compared to the intermediate finishes. The calculated shear strength was greater for the 1μm finish than for the coarser finishes.

2. Greater data point scatter occurs for the finer surface finishes. When the results obtained here are compared with the work of other investigators who have performed tension, push-out and pull-out tests, the test reproducibility seems comparable in all cases. This indicates that reproducibility is probably a function mainly of the interface preparation technique rather than the type of test. The torsion test described here may be more accurate than these other tests, however.
3. The use of the relatively high pressure technique employed here to form the interfaces seems to clearly increase interfacial strength when compared to tests performed by other investigators whose methods more closely parallel clinical techniques. This gives reason for optimism that the concept of pre-forming M/BC interfaces before implantation could be used to enhance interfacial strengths.
4. There do seem to be some differences between implant materials when the other conditions of metal surface preparation, interface formation, and testing are equivalent. The 316L interfaces are the strongest, although this finding is not significant for the practical case of total hip replacement design because very few of these are fabricated from austenitic stainless steels. This material was included in the testing program to determine whether or not the material used to make the interface was a variable which affected torsional strength. Except at 15μm, normalized yielding torque was about 1/3 higher for the Co-Cr-Mo alloy than for the Ti-6Al-4V ELI in the non-treated condition. Interfacial shear strength for the non-treated Co-Cr-Mo alloy at 1μm was about 50% greater than that of the Ti alloy. However, similar values were observed for the other three roughnesses. Investigators who have examined M/BC interfaces with a different loading mode have ranked the materials differently.

5. Only weak evidence was found, if any exists at all, to indicate that sterilization and passivation exert an influence on M/BC interface strength. Due to the potentially great influence that such procedures could have on the electrochemical behavior of the metals involved due to surface alteration, this finding may seem surprising. However, electrochemical effects such as breakdown of passivity and consequent increase of corrosion current are very sensitive to localized inhomogeneities and defects in the passive film. Although, for the mechanical behavior of an interface, such film defects could possibly be stress concentrations and could result in some decrease in strength, M/BC interface mechanical behavior would be more affected by the overall surface contact area. Another possible explanation is that the surfaces were already well passivated, so that the treatment had little additional affect.
6. In a very preliminary test, interfacial strength seemed to depend upon twist rate.
7. A rigorous cleaning procedure for the removal of both organic and inorganic contaminants seemed, in a preliminary test, to offer the possibility of increasing interfacial strength.
8. Some samples tested at a cure time of two days produced different strength results than those tested at cure times of four days or more. Thus, low cure time tests should be avoided. Changes with cure time have been observed by other investigators as well which are consistent with this finding. It should be pointed out that the interfacial bond strength values which appear in the literature are often determined after a one day cure time.

REFERENCES

1. W. Barb, J. B. Park, G. H. Kenner, and A. F. von Recum, "Intermedullary Fixation of Artificial Hip Joints with Bone Cement-Precoated Implants. I. Interfacial Strengths," J. Biomed. Mater. Res., 16, 447-58, 1982.
2. P. W. R. Beaumont and B. Plumpton, "The Strength of Acrylic Bone Cements and Acrylic Cement-Stainless Steel Interfaces," J. Mater. Sci., 12, 1853-6, 1977.
3. J. D. Bentkover and P. G. Drew, "Cost Benefit/Cost Effectiveness of Medical Technologies: A Case Study of Orthopedic Joint Implants," Case Study No. 14, Background Paper No. 2 in _The Implication of Cost-Effectiveness Analysis of Medical Technology_, OTS, Sept. 1981.
4. P. W. R. Beaumont and R. J. Young, "Strength and Fracture of Acrylic Bone Cement and Cement-Metal Interfaces," Plastics and Rubber: Materials and Applications, 2-6 Feb. 1977.
5. K. J. Bundy, "Investigation of Stress Analyses and the Metal/Bone Cement Interface in Total Hip Replacement Prostheses" in A. C. Fraker, A. W. Ruff, and K. J. Bundy (with S. A. Demontigny, P. Sung, A. C. Van Orden, and K. M. Speck), _Metallurgical Studies of Interface Bonding on Implant Alloys_, NBSIR 82-2563 (FDA), October, 1982a.
6. K. J. Bundy, "A Torsion Test for the Metal/Bone Cement Interface" submitted to Journal of Biomedical Materials Research, November, 1982b.
7. D. R. Carter, R. Vasu, D. M. Spengler, and R. T. Dueland, "Stress Fields in the Unplated and Plated Femur Calculated from _In Vivo_ Strain Measurements," J. Biomech., _14_, 63-70, 1981.
8. E. Y. S. Chao and M. B. Coventry, "Fracture of the Femoral Component After Total Hip Replacement," J. Bone Jt. Surg., 63-A, 1078-94, 1981.

9. J. Charnley, "Fracture of Femoral Prostheses in Total Hip Replacement. A Clinical Study," Clin. Orthop. and Rel. Res., 111, 105-20, 1975.

10. C. L. Compere and J. L. Lewis (eds.) Proc. Workshop on Internal Joint Replacement, Northwestern U., March 3-5, 1977.

11. S. Cowin, "Continuum Models of the Adaptation of Bone to Stress," in Mechanical Properties of Bone (ed. S. Cowin), Jt. ASME-ASCE Appl. Mech., Fluids Eng., and Bioeng. Conf., Boulder, CO, June 22-24, 1981, AMD-Vol. 45, ASME, NY 193-210.

12. S. C. Cowin and K. Firoozbakhsh, "Bone Remodeling of Diaphysial Surfaces Under Constant Load: Theoretical Predictions," J. Biomech., 14, 471-84, 1981.

13. S. C. Cowin and R. R. Nachlinger, "Bone Remodeling III: Uniqueness and Stability in Adaptive Elasticity Theory," J. Elasticity, 8, 285-95, 1978.

14. S. C. Cowin and W. C. Van Buskirk, "Surface Bone Remodeling Induced by A Medullary Pin," J. Biomech., 12, 269-76, 1979.

15. R. D. Crowninshield, R. A. Brand, R. C. Johnston, and D. R. Pedersen, "An Analysis of Collar Function and the Use of Titanium in Femoral Prostheses," Clin. Orthop. and Rel. Res., 158, 270-7, 1981.

16. G. E. Dieter, Mechanical Metallurgy, McGraw-Hill, N.Y., 2nd ed., p. 381, 1976.

17. A. S. Greenwald and A. H. Wilde, "Some Observations on the Interface Strength of Bone Cement," Biomechanics Laboratory Report 002-74, Cleveland Clinic Foundation, 1974.

18. L. B. Greszczuk, "Theoretical Studies of the Mechanics of the Fiber-Matrix Interface in Composites," Interfaces in Composites, STP 452, ASTM, 42-58, Phil., 1969.

19. D. H. Hegedus and S. C. Cowin, "Bone Remodeling I: Theory of Adaptive Elasticity," J. Elasticity, 6, 313-26, 1976a.

20. D. H. Hegedus and S. C. Cowin, "Bone Remodeling II: Small Strain Adaptive Elasticity," J. Elasticity, 6, 337-52, 1976b.

21. N. J. Holm, "The Relaxation of Some Acrylic Bone Cements, "Acta Orthop. Scand., 51, 727-31, 1980.

22. R. Y. Hori, J. L. Lewis, J. R. Zimmerman, and C. L. Compere, "The Number of Total Joint Replacements in the United States," Clin. Orthop. and Rel. Res., 132, 46-52, 1978.

23. R. Huiskes, "Stress Analyses of Implanted Orthopaedic Joint Prostheses for Optimal Design and Fixation," Acta Orthopaedica Belgica, 46, 711-27, 1980.

24. J. C. Keller, E. P. Lautenschlager, G. W. Marshall, and P. R. Meyer, "Factors Affecting Surgical Alloy/Bone Cement Interface Adhesion," J. Biomed. Mater. Res., 14, 639-51, 1980.

25. J. L. Kelsey, "Epidemiology and Impact," Total Hip Joint Replacement, NIH Consensus Development Conf., Bethesda, March 1-3, 1982.

26. W. R. Krause, J. Miller, and P. Ng, "The Viscosity of Acrylic Bone Cements," J. Biomed. Mater. Res., 16, 219-43, 1982.

27. L. E. Lanyon, I. L. Paul, C. T. Rubin, E. L. Thrasher, R. DeLaura, R. M. Rose, and E. L. Radin, "_In Vivo_ Strain Measurements from Bone and Prosthesis Following Total Hip Replacement," J. Bone Jt. Surg., 63-A, 989-1001, 1981.

28. G. M. McNeice, P. Eng., and H. C. Amstutz, "Finite Element Studies in Hip Reconstruction," in _Biomechanics_ V, (ed. P. Komi), 394-405, 1976.

29. S. Pal and S. Saha, "Stress Relaxation and Creep Behavior of Normal and Carbon Fibre Reinforced Acrylic Bone Cement," Biomaterials, 3, 93-6, 1982.

30. J. B. Park, A. F. von Recum, and G. E. Gratzick, "Precoated Orthopedic Implants with Bone Cement," Biomat. Med. Dev. Art. Org., 7, 41-53, 1979.

31. J. B. Park, W. Barb, G. H. Kenner, and A. F. von Recum, "Intramedullary Fixation of Artificial Hip Joints With Bone Cement-Precoated Implants II. Density and Histological Study," J. Biomed. Mater. Res., 16, 459-70, 1982.

32. S. Raab, A. M. Ahmed, and J. W. Provan, "The Quasistatic and Fatigue Performance of the Implant/Bone Cement Interface," J. Biomed. Mater. Res., 15, 159-82, 1981.

33. S. Raab, A. M. Ahmed, and J. W. Provan, "Thin Film PMMA Precoating for Improved Implant Bone-Cement Fixation," J. Biomed. Mater. Res., 16, 679-704, 1982.

34. G. C. Sih, E. T. Moyer, and A. T. Berman, "Analytical Modeling of Bone-Cement Interface and Failure Prediction," Eng. Frac. Mech., 14, 779-87, 1981.

35. R. P. Welsh, R. M. Pilliar, and I. MacNab, "Surgical Implants - the Role of Surface Porosity in Fixation to Bone and Acrylic," J. Bone Jt. Surg., 53-A, 963-77, 1971.

36. W. E. White, J. H. Wedge, and C. M. Sargent, "Failure Analysis of a Charnley-Muller Total Hip Replacement Prosthesis," Microstructural Science, 7, 27-39, 1979.

APPENDIX 1

MATERIALS, SURFACE FINISH AND PRE-TREATMENT PROCEDURES, AND INTERFACE PREPARATION AND TESTING CHARACTERISTICS

Spec. No.	Material	Surface Finish	L_{ac} (cm)	Sterilized and Passivated?	t_c (days)	Remarks
11	316L	15μm	2.41	no	4	
12	316L	15μm	2.25	no	4	
13	Ti-6Al-4V ELI	15μm	2.41	no	4	
14	Ti-6Al-4V ELI	15μm	2.64	no	5	
15	Ti-6Al-4V ELI	15μm	2.39	no	5	
16	316L	15μm	2.55	no	5	
17	Ti-6Al-4V ELI	15μm	2.76	no	5	
18	316L	15μm	2.60	no	5	
19	Ti-6Al-4V ELI	15μm	2.23	no	19	
20	316L	15μm	2.70	no	19	
21	Ti-6Al-4V ELI	grit blasted	2.69	no	19	
22	Ti-6Al-4V ELI	15μm	2.97	no	19	
23	316L	15μm	2.48	sterilized only	19	
24	316L	15μm	2.50	no	19	
25	Ti-6Al-4V ELI	grit blasted	2.81	no	5	
26	Ti-6Al-4V ELI	grit blasted	1.97	no	5	
27	316L	1μm	2.47	no	5	
28	316L	15μm	2.64	sterilized only	5	
29	316L	15μm	1.52	yes	5	
30	Ti-6Al-4V ELI	grit blasted	2.60	no	5	
31	Co-Cr-Mo	15μm	2.57	no	5	
32	Ti-6Al-4V ELI	15μm	2.63	yes	5	
33	Co-Cr-Mo	15μm	2.77	no	5	
34	316L	1μm	1.78		5	
35	Ti-6Al-4V ELI	15μm	2.28	yes	2	pt 12 d. before test
36	Co-Cr-Mo	15μm	2.32	no	2	
37	316L	1μm	2.90		2	
38	Co-Cr-Mo	1μm	2.83	no	2	
39	Ti-6Al-4V ELI	1μm	$2.62 < L_{ac} < 3.09$	no	43	acrylic poorly plac
40	316L	15μm	2.79	no	2	
41	Co-Cr-Mo	1μm	2.96	no	2	
42	Co-Cr-Mo	15μm	2.65	yes	2	
43	316L	15μm	2.81	no	2	strain rate=50°/sec
44	Ti-6Al-4V ELI	1μm	2.84	no	2	
45	Co-Cr-Mo	6μm	2.27	no	6	
46	Co-Cr-Mo	1μm	2.27	no	6	
47	Co-Cr-Mo	1μm	1.60	no	6	
48	Ti-6Al-4V ELI	6μm	1.96	no	6	
49	Ti-6Al-4V ELI	15μm	1.45	yes	6	
50	316L	6μm	1.98	no	6	
51	316L	1μm	2.47	no	6	
52	Ti-6Al-4V ELI	1μm	2.33	no	6	
53	Ti-6Al-4V ELI	6μm	1.87	no	6	
54	316L	6μm	2.72	no	5	
55	Co-Cr-Mo	15μm	2.37	no	5	

APPENDIX 1

Spec. No.	Material	Surface Finish	L_{ac} (cm)	Sterilized and Passivated	t_c (days)	Remarks
56	Co-Cr-Mo	15μm	2.64	yes	5	
57	Co-Cr-Mo	15μm	2.12	yes	5	
58	316L	15μm	2.69	no	5	strain rate=50°/sec
59	Ti-6Al-4V ELI	15μm	4.09	no	5	
60	Ti-6Al-4V ELI	15μm	0.87	no	5	
61	Co-Cr-Mo	6μm	2.47	no	5	
62	Ti-6Al-4V ELI	15μm	1.67	no	5	
63	Co-Cr-Mo	grit blasted	2.57	no	5	
64	316L	15μm	2.06	no	6	strain rate=2.81°/sec
65	316L	6μm	2.10	no	6	
66	Co-Cr-Mo	grit blasted	2.44	no	6	
67	Co-Cr-Mo	grit blasted	$2.22<L_{ac}<3.71$	no	6	acrylic poorly placed
68	316L	grit blasted	2.32	no	6	
69	316L	grit blasted	2.57	no	6	
70	316L	grit blasted	2.61	no	6	
71	Ti-6Al-4V ELI	15μm	2.75	no	6	exposed to saline solution for 1 hr. prior to test
72	Ti-6Al-4V ELI	15μm	2.72	no	6	same as 71
73	Ti-6Al-4V ELI	15μm	1.66	no	6	
74	Co-Cr-Mo	6μm	2.68	no	6	
75	316L	1μm	2.30	yes	6	
76	316L	1μm	2.65	yes	6	
77	Ti-6Al-4V ELI	15μm	-	no	-	rigorous cleaning procedure followed
78	Ti-6Al-4V ELI	15μm	2.04	no	7	same as 77
79	Ti-6Al-4V ELI	15μm	2.48	no	7	same as 77
80	Ti-6Al-4V ELI	6μm	2.55	no	7	
81	Ti-6Al-4V ELI	1μm	2.39	yes	7	
82	Ti-6Al-4V ELI	1μm	2.15	no	7	
83	Co-Cr-Mo	1μm	2.34	yes	5	
84	Ti-6Al-4V ELI	1μm	2.20	no	5	
85	Co-Cr-Mo	1μm	2.77	yes	5	
86	Ti-6Al-4V ELI	1μm	2.65	yes	5	
87	Co-Cr-Mo	1μm	2.66	no	5	

L_{ac} - length of the acrylic block

t_c - cure time

APPENDIX 2

MECHANICAL PROPERTIES OF METAL/BONE CEMENT INTERFACES

Spec. No.	T^m/L_{ac} (N)	T^m (N-m)	τ_{is} (MPa)	β (cm^{-1})	γ_y (degrees)	G_{eff} (N-m/deg.)	G_{eff}/L_{ac} (N/deg.)
11	148	3.56	6.46	1.15	1.21	2.94	122
12	150	3.37	6.20	1.15	1.25	2.69	120
13	252	6.08	15.6	1.62	3.77	1.61	66.9
14	138	3.64	9.35	1.62	3.50	1.04	39.4
15	152	3.64	9.33	1.62	2.18	1.67	69.8
16	150	3.83	6.94	1.15	1.48	2.59	102
17	151	4.15	10.65	1.62	2.72	1.53	55.4
18	145	3.76	6.82	1.15	2.25	1.67	64.4
19	151	3.37	8.66	1.62	1.95	1.73	77.6
20	866	23.4	42.4	1.15	10.8	2.17	80.3
21	354	9.55	8.72	0.507	5.46	1.75	64.5
22	123	3.64	9.34	1.62	1.72	2.12	71.5
23	147	3.64	6.60	1.15	1.23	2.97	120
24	149	3.73	6.76	1.15	1.25	3.00	120
25	324	9.08	8.16	0.507	4.88	1.86	66.3
26	192	3.78	3.97	0.507	2.12	1.78	90.6
27	758	18.7	43.8	1.48	8.13	2.30	93.3
28	149	3.93	7.12	1.15	1.37	2.87	109
29	263	4.00	7.80	1.15	1.72	2.34	153
30	322	8.38	7.74	0.507	3.98	2.11	81.0
31	157	4.03	7.30	1.15	1.56	2.58	100
32	139	3.67	9.42	1.62	2.15	1.71	64.8
33	188	5.21	9.46	1.15	1.44	3.63	131
34	1020	18.2	43.0	1.48	7.09	2.57	144
35	91.4	2.09	5.35	1.62	1.37	1.52	66.8
36	444	10.3	18.9	1.15	3.88	2.65	114
37	247	7.16	16.8	1.48	2.69	2.66	91.7
38	279	7.89	18.5	1.48	2.33	3.39	120
39	54.4*	1.68	5.56	2.10	0.94	1.79	57.9
40	395	11.0	20.0	1.15	5.09	2.17	77.7
41	488	14.4	33.8	1.48	6.14	2.35	79.5
42	113	3.01	5.45	1.15	1.35	2.23	84.1
43	677	19.0	34.4	1.15	9.42	2.02	71.9
44	180	5.11	16.9	2.10	3.59	1.42	50.2
45	126	2.85	6.18	1.37	1.36	2.10	92.8
46	682	15.5	36.3	1.48	4.31	3.60	158
47	329	5.26	12.5	1.48	1.44	3.67	229
48	171	3.36	10.3	1.94	1.71	1.97	100
49	206	2.98	7.82	1.62	1.85	1.61	111
50	114	2.25	4.88	1.37	0.90	2.51	127
51	225	5.56	13.0	1.48	1.71	3.26	132
52	205	4.78	15.8	2.10	2.54	1.89	80.7
53	133	2.49	7.62	1.94	1.41	1.76	94.2
54	143	3.89	8.43	1.37	1.25	3.13	115
55	210	4.98	9.13	1.15	1.43	3.48	147
56	162	4.27	7.75	1.15	1.12	3.83	145

APPENDIX 2 (Cont.)

MECHANICAL PROPERTIES OF METAL/BONE CEMENT INTERFACES

Spec. No.	T^m/L_{ac} (N)	T^m (N-m)	τ_{is} (MPa)	β (cm^{-1})	γ_y (degrees)	G_{eff} (N-m/deg.)	G_{eff}/L_{ac} (N/deg.)
57	142	3.01	5.57	1.15	1.01	3.00	141
58	420	11.3	20.5	1.15	5.10	2.21	82.3
59	161	6.60	16.9	1.62	2.75	2.40	58.7
60	245	2.14	6.17	1.62	1.21	1.77	203
61	272	6.72	14.6	1.37	1.71	3.93	159
62	301	5.04	13.1	1.62	3.17	1.59	95.1
63	378	9.72	7.93	0.399	2.66	3.65	142
64	680	14.0	25.9	1.15	5.65	2.48	120
65	633	13.3	28.7	1.37	5.08	2.61	125
66	403	9.85	8.26	0.399	2.49	3.96	162
67	210*	7.78	5.44	0.399	2.43	3.20	86.2
68	575	13.4	12.0	0.434	4.84	2.76	119
69	554	14.2	12.1	0.434	5.22	2.73	106
70	556	14.5	12.3	0.434	5.75	2.53	96.8
71	146	4.01	10.3	1.62	2.25	1.78	64.6
72	136	3.69	9.46	1.62	2.04	1.81	66.6
73	153	2.54	6.60	1.62	1.49	1.71	103
74	256	6.87	14.9	1.37	1.94	3.54	132
75	237	5.47	12.8	1.48	2.15	2.55	111
76	199	5.29	12.4	1.48	1.97	2.69	101
77							
78	258	5.26	13.5	1.62	2.99	1.76	86.1
79	191	4.76	12.2	1.62	2.70	1.77	71.0
80	182	4.66	14.3	1.94	2.34	1.99	77.9
81	164	3.92	13.0	2.10	2.20	1.79	74.6
82	202	4.33	14.3	2.10	2.44	1.78	82.6
83	193	4.50	10.5	1.48	1.43	3.15	135
84	174	3.82	12.7	2.10	2.20	1.74	79.0
85	163	4.50	10.5	1.48	1.07	4.21	152
86	168	4.45	14.7	2.10	2.28	1.95	73.7
87	245.	6.52	15.3	1.48	1.52	4.29	161

*based on maximum L_{ac} for this sample.

APPENDIX 3

MECHANICAL PROPERTIES OF METAL/BONE CEMENT INTERFACES CLASSIFIED ACCORDING TO MATERIALS AND SURFACE FINISH

A. 316L

Surface Condition	Specimen Number	T^m/L_{ac} (N)	T^m (N-m)	τ_{is} (MPa)	G_{eff}/L_{ac} (N/degree)	Remarks
Grit blasted	68	575	13.4	12.0	119	
	69	554	14.2	12.1	106	
	70	556	14.5	12.3	96.8	
15μm	11	148	3.56	6.46	122	
	12	150	3.37	6.20	120	
	16	150	3.83	6.94	102	
	18	145	3.76	6.82	64.4	
	20	866	23.4	42.4	80.3	artifact due to accidental plastic deformation
	24	149	3.73	6.76	120	
	40	395	11.0	20.0	77.7	t_c = 2 days
	43	677	19.0	34.4	71.9	t_c = 2 days; strain rate=50°/
	58	420	11.3	20.5	82.3	strain rate = 50°/sec
	64	680	14.0	25.9	120	strain rate = 2.81°/sec
	23	147	3.64	6.60	120	sterilized
	28	149	3.93	7.12	109	sterilized
	29	263	4.00	7.80	153	sterilized & passivated
6μm	50	114	2.25	4.88	127	
	54	143	3.89	8.43	115	
	65	633	13.3	28.7	125	

APPENDIX 3

A. 316L (continued)

Surface Condition	Specimen Number	T^m/L_{ac} (N)	T^m (N-m)	τ_{is} (MPa)	G_{eff}/L_{ac} (N/degree)	Remarks
1μm	27	758	18.7	43.8	93.3	
	34	1020	18.2	43.0	144	
	51	225	5.56	13.0	132	
	37	247	7.16	16.8	91.7	t_c = 2 days
	75	237	5.47	12.8	111	sterilized & passivated
	76	199	5.29	12.4	101	sterilized & passivated

APPENDIX 3

B. Co-Cr-Mo

Surface Condition	Specimen Number	T^m/L_{ac} (N)	T^m (N-m)	τ_{is} (MPa)	G_{eff}/L_{ac} (N/degree)	Remarks
Grit blasted	63	378	9.72	7.93	142	
	66	403	9.85	8.26	162	
	67	210*	7.78	5.75	86.2	poorly placed acrylic
15μm	31	157	4.03	7.30	100	
	33	188	5.21	9.46	131	
	55	210	4.98	9.13	147	
	36	444	10.3	18.9	114	t_c = 2 days
	42	113	3.01	5.45	84.1	t_c = 2 days;sterilized & passivated
	56	162	4.27	7.75	145	sterilized & passivated
	57	142	3.01	5.57	141	sterilized & passivated
6μm	45	126	2.85	6.18	92.8	
	61	272	6.72	14.6	159	
	74	256	6.87	14.9	132	
1μm	46	682	15.5	36.3	158	
	47	329	5.26	12.5	229	
	87	245	6.52	15.3	161	
	38	279	7.89	18.5	120	t_c = 2 days
	41	488	14.4	33.8	79.5	t_c = 2 days
	83	193	4.50	10.5	135	sterilized & passivated
	85	163	4.50	10.5	152	sterilized & passivated

* - based on the maximum L_{ac} for this sample.

Appendix 3

C. Ti-6Al-4V ELI

Surface Condition	Specimen Number	T^m/L_{ac} (N)	T^m (N-m)	τ_{is} (MPa)	G_{eff}/L_{ac} (N/degree)	Remarks
Grit blasted	21	354	9.55	8.72	64.5	
	25	324	9.08	8.16	66.3	
	26	192	3.78	3.97	90.6	
	30	322	8.38	7.74	81.0	
15μm	13	252	6.08	15.6	66.9	
	14	138	3.64	9.35	38.0	
	15	152	3.64	9.33	69.8	
	17	151	4.15	10.6	55.4	
	19	151	3.37	8.66	77.6	
	22	123	3.64	9.34	71.5	
	59	161	6.60	16.9	58.7	
	60	245	2.14	6.17	203	
	62	301	5.04	13.1	95.1	
	73	153	2.54	6.60	103	
	32	139	3.67	9.42	64.8	sterilized & passivated
	49	206	2.98	7.82	111	sterilized & passivated
	35	914	2.09	5.35	66.8	t_c = 2 days (sterilized & passivated 12 days prior to test)
	71	146	4.01	10.3	64.6	tested after approx. 1 hr. exposure to saline solution
	72	136	3.69	9.46	66.6	same as 71
	78	258	5.26	13.5	86.1	rigorously cleaned surface
	79	191	4.76	12.2	71.0	rigorously cleaned surface
6μm	48	171	3.36	10.3	100	
	53	133	2.49	7.62	94.2	
	80	182	4.66	14.3	77.9	

APPENDIX 3

C. Ti-6Al-4V ELI (continued)

Surface Condition	Specimen Number	T^m/L_{ac} (N)	T^m (N-m)	τ_{is} (MPa)	G_{eff}/L_{ac} (N/degree)	Remarks
1μm	52	205	4.78	15.8	80.7	
	82	202	4.33	14.3	82.6	
	84	174	3.82	12.7	79.0	
	39	54.4*	1.68	5.56	57.9	poorly placed acrylic
	44	180	5.11	16.9	50.2	t_c = 2 days
	81	164	3.92	13.0	74.6	sterilized & passivated
	86	168	4.45	14.7	73.7	sterilized & passivated

* - based on the maximum L_{ac} for this sample.

NBS-114A (REV. 2-80)

U.S. DEPT. OF COMM. BIBLIOGRAPHIC DATA SHEET (See instructions)	1. PUBLICATION OR REPORT NO. NBSIR 83-2736	2. Performing Organ. Report No.	3. Publication Date September 1983

4. TITLE AND SUBTITLE

Studies of Interface Bondings on Implant Alloys

5. AUTHOR(S) Anna C. Fraker, Arthur W. Ruff, and Kirk J. Bundy
Jacqueline D. Smith, Robert W. Penn, Ann C. Van Orden

6. PERFORMING ORGANIZATION (If joint or other than NBS, see instructions)

NATIONAL BUREAU OF STANDARDS
DEPARTMENT OF COMMERCE
WASHINGTON, D.C. 20234

7. Contract/Grant No.
22 4795023

8. Type of Report & Period Covered
Oct.,1981-Oct.,1982

9. SPONSORING ORGANIZATION NAME AND COMPLETE ADDRESS (Street, City, State, ZIP)

Bureau of Medical Devices
Food and Drug Administration
Silver Spring, MD

10. SUPPLEMENTARY NOTES

☐ Document describes a computer program; SF-185, FIPS Software Summary, is attached.

11. ABSTRACT (A 200-word or less factual summary of most significant information. If document includes a significant bibliography or literature survey, mention it here)

The work dealth primarily with testing metal/bone cement interface strength using the torsion test which was developed earlier in this project and described in NBSIR 82-2563. The test proved to be a good one and to be reasonably reproducible. The parameters studied to determine their influence on the metal/bone cement interface strength were material type, specimen surface roughness, sterilization and passivation treatments, cure time prior to testing and effects of ultra clean surfaces. Metals used were the alloys, Co-Cr-Mo, Ti-6Al-4V and 316L stainless steel. The bone cement used was Howmedica Surgical Simplex P which is a poly(methyl methacrylate) type. Seventy-seven tests were conducted. The description of these tests, analysis of the results and a discussion of related studies in the technical literature are given in the technical report entitled "An Experimental Investigation of the Torsional Strength of Metal/Bone Cement Interface."

12. KEY WORDS (Six to twelve entries; alphabetical order; capitalize only proper names; and separate key words by semicolons)

Bone cement; interface strength; metals; poly(methyl methacrylate); prosthesis fixation; surfaces; surgical implants.

13. AVAILABILITY

☒ Unlimited
☐ For Official Distribution. Do Not Release to NTIS
☐ Order From Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.
☐ Order From National Technical Information Service (NTIS), Springfield, VA. 22161

14. NO. OF PRINTED PAGES
90

15. Price

USCOMM-DC 6043-P80